A PILOT STUDY OF STERILE SALINE VERSUS REVERSE OSMOSIS WATER IN TRAUMATIC LACERATION WOUND CLEANSING IN EMERGENCY DEPARTMENT IN HOSPITAL UNIVERSITI SAINS MALAYSIA, KELANTAN AND HOSPITAL TENGKU AMPUAN AFZAN, PAHANG.

BY

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BAHAGIAN C

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Introduction: Traumatic laceration wound is a common reason for people seeking treatment in emergency care setting. As for current practice, sterile saline is still the most common agent used in cleansing or irrigating the wound in the emergency department. In overseas, there have been studies on alternative cleansing agent particularly tap water, which have showed equal or better outcomes in term of wound infection. There is no previous study been conducted on wound cleansing using Reverse Osmosis water.

Objectives: To compare the rate of wound infection between sterile saline and reverse osmosis water cleansing for traumatic laceration wound.

Method: This study was a multicenter, prospective, randomised controlled trial conducted at two tertiary hospitals. Subjects were a convenience sample of adults presenting with acute simple traumatic laceration requiring wound cleansing. They were randomized using block randomization method to irrigation with ‘sterile saline’ or ‘reverse osmosis’ water. Wounds were closed in the standard fashion. Follow-ups were done on day 5 and 14 after the intervention to assess for outcome or wound infection.

Results: A total of 48 patients (n=48) were selected and randomised into RO water group (n=24) and Saline group (n=20) (4 patients withdrew). The infection rate for sterile saline cleansing was 5% (95% CI -4.55%, 14.55%) compared to RO cleansing which was 4.17% (95% CI -3.83%, 12.17%). Relative risk for RO water group was 0.834 (95%CI 0.056, 12.494) compare to saline group. Fisher’s Exact test showed no significant effect on type of cleansing agent on wound infection.

Conclusion: There was no significant difference between reverse osmosis and saline on wound infection. Reverse osmosis water can be considered as alternative cleansing agent to sterile saline in acute uncomplicated traumatic laceration wounds.

Dr Mohd Hashairi Hj Fauzi : Supervisor

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LIST OF ABBREVIATIONS

HUSM	Hospital Universiti Sains Malaysia
HTAA	Hospital Tengku Ampuan Afzan
ED	Emergency Department
RO	Reverse Osmosis
SS	Sterile Saline
CI	Confidence Interval
MVA	Motor Vehicle Accident

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ABSTRAK

Tajuk: Kajian Pembersihan Luka Trauma di Jabatan Kecemasan: Perbandingan antara Air 'Sterile Saline' (SS) dan Air 'Reverse Osmosis' (RO) di Hospital Universiti Sains Malaysia, Kelantan dan Hospital Tengku Ampuan Afzan, Pahang

Pengenalan : Luka trauma merupakan antara sebab-sebab utama pesakit mendapatkan rawatan kecemasan di hospital atau klinik. Pada masa ini, air 'sterile saline' digunakan sebagai agen utama dalam pembersihan luka trauma di Jabatan Kecemasan. Di luar negara terdapat pelbagai kajian yang telah membuktikan bahawa terdapat alternatif agen pembersihan luka seperti air paip yang menunjukkan kesan yang sama atau lebih baik dari segi kadar jangkitan luka berbanding air 'sterile saline'.Setakat ni masih belum terdapat kajian mengenai permbersihan luka trauma menggunakan air RO.

Objektif : Tujuan utama kajian ini adalah untuk menentukan perbezaan kadar jangkitan luka trauma selepas dibersihkan menggunakan air 'Sterile Saline' atau air 'Reverse Osmosis'.

Kaedah: Kajian ini adalah kajian prospektif, rawak terkawal yang telah dijalankan di dua hospital tertiari. Subjek adalah terdiri daripada pesakit dewasa yang mengalami luka trauma yang akut dan tidak berkomplikasi yang memerlukan pembersihan luka. Mereka telah dirawakkan kepada kumpulan air RO dan kumpulan air sterile saline. Luka akan ditutup mengikut prosedur biasa. Temujanji susulan telah diberikan pada hari ke-5 dan ke-14 selepas intervensi bagi mengkaji tanda-tanda jangkitan pada luka.

Keputusan : Sejumlah 48 orang pesakit (n=48) telah dipilih untuk menyertai kajian ni. Mereka dirawakkan kepada kumpulan ‘Reverse Osmosis’ seramai 24 orang dan kumpulan Sterile Saline seramai 20 orang. 4 pesakit telah menarik diri. Kadar jangkitan bagi kumpulan air saline adalah 5% (95% CI -4.55%, 14.55%) manakala kadar jangkitan bagi kumpulan air RO adalah 4.17 %(95% CI -3.83%, 12.17%). Risiko relatif bagi air Reverse Osmosis adalah 0.834 (95% CI 0.056, 12.494) berbanding Sterile Saline. Ujian ‘Fisher’s Exact’ menunjukkan tiada kesan signifikan jenis air cucian terhadap jangkitan pada luka.

Kesimpulan : Tiada perbezaan yang signifikan antara air reverse osmosis dan saline dalam jangkitan luka. Air RO boleh dipertimbangkan sebagai alternatif air pembersih luka.

ABSTRACT

Title: A Pilot Study of Traumatic Laceration Wound Cleansing in Emergency Department : Saline versus Reversed Osmosis (RO) water, in Hospital Universiti Sains Malaysia(HUSM), Kelantan and Hospital Tengku Ampuan Afzan(HTAA), Pahang

Introduction: Traumatic laceration wound is a common reason for people seeking treatment in emergency care setting. As for current practice, sterile saline is still the most common agent used in cleansing or irrigating the wound in the emergency department. In overseas, there have been studies on alternative cleansing agent particularly tap water, which have showed equal or better outcomes in term of wound infection. There is no previous study been conducted on wound cleansing using Reverse Osmosis water.

Objectives: To compare the rate of wound infection between sterile saline and reverse osmosis water cleansing for traumatic laceration wound.

Method: This study was a multicenter, prospective, randomised controlled trial conducted at two tertiary hospitals. Subjects were a convenience sample of adults presenting with acute simple traumatic laceration requiring wound cleansing. They were randomized using block randomization method to irrigation with ‘sterile saline’ or ‘reverse osmosis’ water. Wounds were closed in the standard fashion. Follow-ups were done on day 5 and 14 after the intervention to assess for outcome or wound infection.

Results: A total of 48 patients (n=48) were selected and randomised into RO water group (n=24) and Saline group (n=20) (4 patients withdrew). The infection rate for sterile saline cleansing was 5% (95% CI -4.55%, 14.55%) compared to RO cleansing which was 4.17% (95% CI -3.83%, 12.17%). Relative risk for RO water group was 0.834 (95%CI 0.056, 12.494) compare to saline group. Fisher's Exact test showed no significant effect on type of cleansing agent on wound infection.

Conclusion: There was no significant difference between reverse osmosis and saline on wound infection. Reverse osmosis water can be considered as alternative cleansing agent to sterile saline in acute uncomplicated traumatic laceration wounds.

INTRODUCTION

As for other developing and some developed countries, trauma is still an increasing problem, and it is the leading cause of morbidity and mortality in the under 40s age group in Malaysia. Accidents are the third most common cause of admission to Ministry of Health hospitals. For every person killed, there are at least two who survive with serious permanent disabilities. In 2002, there were 15,100 deaths due to injuries with 4,900 from road traffic accidents (Sabariah *et al.*, 2008).

Traumatic wounds are one of the commonest reasons for a visit to the emergency department and healthcare facilities worldwide. In the USA, traumatic wounds are the second most common reason patients seeking medical care, with emergency departments treating an estimated 11 million cases each year (Weiss *et al.*, 2013). In Malaysia, there is still lack of specific data or research on traumatic wounds, particularly acute traumatic wounds. The main goal in the management of wounds is to achieve rapid healing with optimal functional and cosmetic results (Singer and Dagum, 2008).

In managing an acute traumatic wound, irrigation is the most important step in reducing bacterial contamination and potential for wound infection (Trott, 2012). Many studies and consensuses have showed that irrigation reduces infection rates among patient with traumatic wounds. However, there are several controversial issues and questions pertaining to acute wound management, for examples the type of solutions to be used for irrigation, the role of antiseptic solutions in superficial wound, the timing prior to the presentation to ED to be considered as acute wound, the volume of fluid to be used for irrigation, and the most accurate criteria to consider the wound as infected. These areas are still much debatable and need further clinical trials.

The aim of this study was to compare the significant difference of two different cleansing agents – the usual and standard Sterile Saline (SS) versus the commonly drinkable Reverse Osmosis (RO) water. The main outcome was the infection rate. There have been no trials conducted using RO before. Previously at least seven trials (Angeras 1992, Griffiths 2001, Bansal 2002, Godinez 2002, Valente 2003, Moscati 2007 and Weiss 2013) were done comparing normal saline with tap water in wound cleansing. All of them demonstrated that infection rate in tap water group was slightly lower or equal to the normal saline group (Fernandez *et al.*, 2008). Tap water also was proven to be an effective alternative to normal saline solution for wound irrigation in children (Valente *et al.*, 2003)

The main difficulty with the use of tap water is to ascertain the source, sterility (Sibbald *et al*, 2000) and differences in purification procedures in many countries (Whaley *et al*, 2004). Most of the literatures accepted that in order to use tap water as an irrigation solution, it must be of drinkable quality.

Reverse Osmosis(RO) water is produced from the purification technology that uses a semi permeable membrane. RO water is free from unwanted odours and it is also colourless. It does not contain minerals that are dissolved unlike other water produced by different filtration systems. In RO process, toxic chemicals are absorbed making the water output fit for human consumption. Throughout the process of RO, contaminant that makes the water taste unpleasant is removed (Crittenden 2005). Up to date, there is no study or trial being done using RO water as wound irrigating agent.

Besides infection rate, this study was intended to look into cost differences between the two groups. Since wound cleansing is a daily and a common procedure done in ED worldwide, cost management is an important issue as for all other health care aspects. The results of a study done in the United State (US) demonstrated an adjusted annual saving of US$ 65,600,000 if wounds were irrigated using tap water instead of saline (Moscati *et al.*, 2007).

METHODOLOGY

Study design

This was a multicentre, prospective, randomised controlled trial using a convenience sample of adults presenting to the ED with acute uncomplicated laceration wounds requiring wound cleansing. In this study, the patients, treating doctors and the assessor were all blinded to avoid selection and recall bias. The study protocol has been reviewed and approved by the 2 instituitions : **Human Research Ethics Committee Universiti Sains Malaysia (HREC) (**Protocol code: **USM/JEPeM/140232)** and **Medical Research & Ethics Committee (MREC), Ministry of Health Malaysia (**Sudy I/D: NMRR-**14-955-21527 (IIR).** Informed consent was obtained before study participation.

Study Location and Population

The source populations were patients in Emergency Department at two tertiary hospitals in east coast of peninsular Malaysia which are Hospital Universiti Sains Malaysia (HUSM) in Kelantan and Hospital Tengku Ampuan Afzan (HTAA) in Pahang. Each has Emergency Physicians, emergency medical trainees, medical students and paramedics working under the supervision of attending emergency physicians.

Study period

The study was conducted from 1st of October 2014 to 30 September 2015

Study materials

Listed were the materials that had been used for this trial:

1) Sterile dressing set – comprising of kidney dish, pot , gauze , cotton
2) 50cc syringe
3) Sterile gloves
4) Standard non-absorbable suture (where applicable)
5) 1000ml Sodium chloride 0.9% irrigation solution (RM 3.30 per bottle)
6) RO water – bottled RO water with 500ml volume per bottle was used in this study. The RO water was purchased in quantity of 24 bottles per box from 'Kedai Rakyat 1Malaysia' with an average cost of RM 0.27 per bottle. It's water source was approved by Ministry of Health Malaysia (Approval Number: KKM 163 (52/C/13)

No antiseptics were used in this study.

Sampling frame

All patients 18 years and older of age, who presented to the ED with traumatic laceration wounds and fulfilled the inclusion and exclusion criteria.

Inclusion criteria are as follow:

- Patients 18 years and older of age, who presented to the ED with an uncomplicated traumatic soft tissue laceration wounds.
- Patients have to provide a telephone number for follow-up in order to be enrolled in the study.

- Informed consent obtained by an assigned doctor (NOT the treating doctor/investigator) in Emergency department (dressing room) upon decision for dressing has been made.
-

Exclusion criteria are as follow:

- Any underlying immunocompromised conditions (eg, diabetes mellitus, chronic kidney disease, chronic alcoholism, primary immune disorder, steroid use or chemotherapy)
- Any current use of antibiotics/concurrent infections
- Puncture or bite wounds
- Any complicated wounds e.g: underlying tendon, joint or bone involvement, or any wound needing surgical debridement
- No concurrent major injury e.g: severe head injury, intraabdominal injury or chest injury
- Wounds more than 9 hours old.

Sample size calculation

As this is a pilot study, the targeted number of subjects was set at a minimum of 20 per interventional group. Burns and Grove (2005) and Polit and Back (2004) make no specific recommendations on sample size for pilot study. Others recommend obtaining approximately 10 participants or 10% of the final study size (Hertzog, 2008). A total of 48 patients were initially selected in this study. However 4 patients were excluded after they did not give consent for participation.

Statistical analysis

Data analysis was done by SPSS version 22 for data entry and analyses. The demographics and clinical factors were analysed with descriptive statistics (frequency and percentage). Chi-Square test was used for comparison between saline and RO water. The comparison of infection rate in both intervention groups was determined by using Fisher's Exact Test. 95% confident interval (CI) of the proportion of infection for RO water and saline was then calculated manually. P is proportion of infection in each group, n is sample size of each group and z is 1.96 by putting level of confidence is 95%.

Sampling method

All patients presented to emergency department with traumatic laceration wound were screened according to the inclusion and exclusion criteria as mentioned above.

Those who have fulfilled the criteria were randomized using block randomization system in which data collection forms arranged in block of interventional and control group so that in a given time, the sample size of both group will be comparable and equal in number. Here, a block size of 4 was chosen. Balanced combinations with 2 S (Saline Water) and 2 R (RO water) subjects were calculated as 6 combination blocks (1= SSRR, 2= SRSR, 3= SRRS, 4= RSSR, 5= RSRS, 6= RRSS). Then sequence of block will be randomly selected and arranged using computer-programme.

Wound cleansing was conducted by an assigned medical assistant/staff nurse appointed for each shift. 1 litre of saline water or RO water was used to irrigate the wound. Each sample will be put into a steriled container e.g pot/kidney dish. Then irrigation was done using 50-ml syringe and 18-gauge branula catheter. In this study low pressure irrigation was applied.

Irrigation and cleansing was done as per standard of wound management procedure. To avoid bias, patients, the treating doctors and assessor were all blinded.

In order to control other possible source of infection, dressor had to wear sterile gloves, approriate personal protective equipment/wear and used sterile wound cleansing set. All other risks of infection as per exclusion criteria were screened beforehand by detailed history and physical examination.

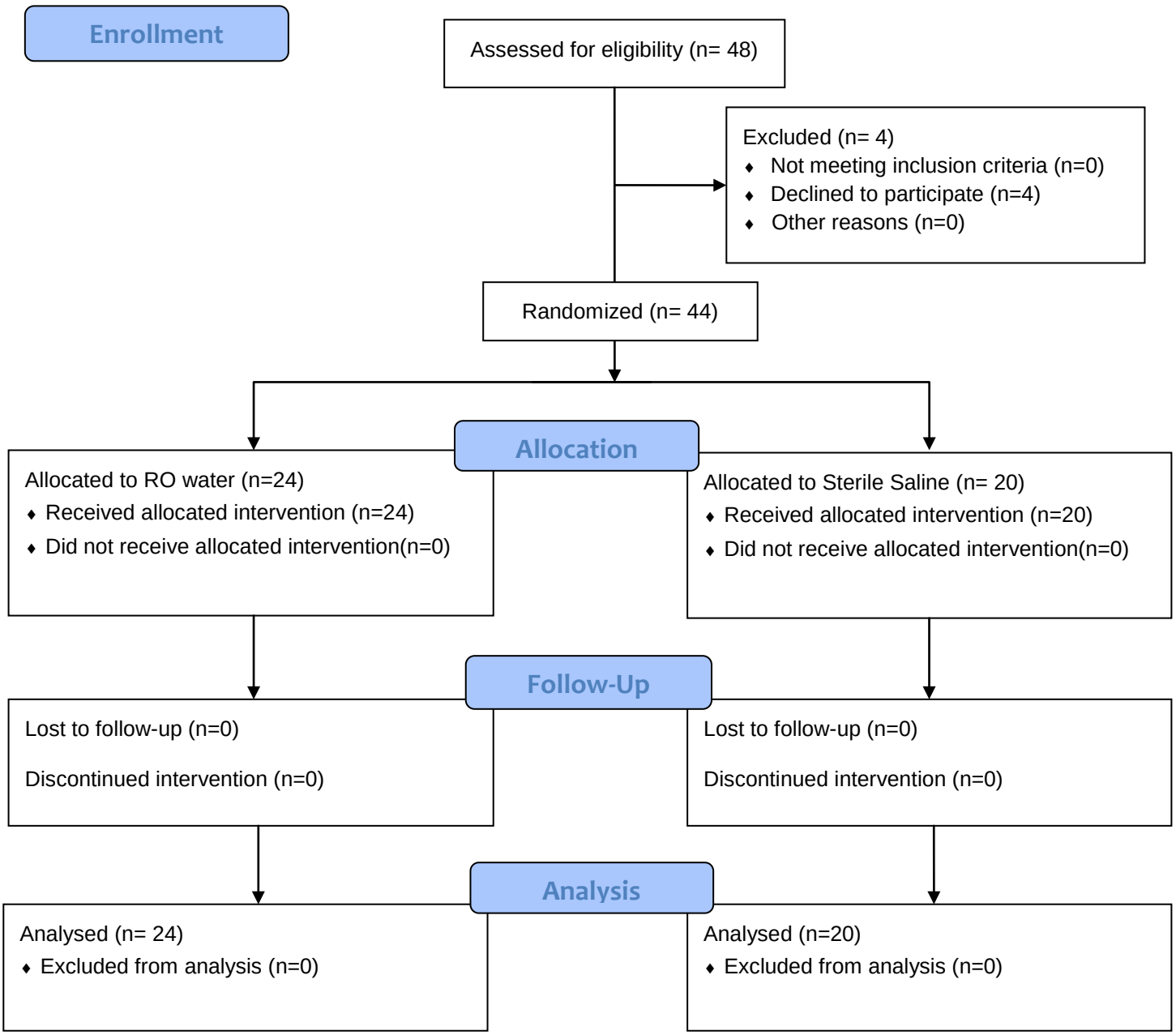
Patients were instructed to return to ED in 5 and 14 days for follow-up to review the wound. Follow-up was done by the researcher. Patients were given appointment to the Emergency Department Green Zone for wound review. Day 5 was chosen as first follow up in view of the ending of inflammatory phase of wound healing process. On Day 14, the progress of wound healing can be monitored.

A wound was classified as infected if it exhibited any of the following criteria (Weiss, 2013):

- Stitch abscess as evidenced by purulent exudates or pus discharge surrounding a stitch or fluctuant swelling over stitched area.
- Erythema or redness area surrounding the wound.
- Gross exudates as evidenced by marked fluid or semisolid that has exuded out of a tissue/wound.
- Fever ≥38°C (increase in body temperature of equal to or more than 38 degree Celsius).

Patients were informed and educated regarding criteria during the initial visit. Patients have been advised to come back immediately if he/she developed any of the signs of the infected wound at any point of during the study.

Figure 1: CONSORT diagram of subject enrollment



RESULTS

A total of 48 subjects were selected in this trial from both hospitals. However, four of them were excluded as they refused to participate. Forty-four subjects were enrolled with 20 in the saline group and 24 in the RO group. The demographics and wound characteristics analysed includes gender, age of subjects, site of wound, size of wound, mechanism of injury, timing of injury to cleansing and requirement of suturing **(Table 1)**.

Table 1: Demographic and wound characteristic of participants (N=44)

Variable	**Saline cleansing**		**RO cleansing**		**P value***
	n	(%)	n	(%)	
Gender					
Male	13	65.0	19	79.2	0.293
Female	7	35.0	5	20.8	
Age					
Less than 21	5	25.0	7	29.2	0.752
21-30	7	35.0	10	41.6	
more than 30	8	40.0	7	29.2	
Site of wound					
Neck/head	10	50.0	10	41.7	0.580
Limbs	10	50.0	14	58.3	
Suturing					
Yes	13	65.0	19	79.2	0.293
No	7	35.0	5	20.8	
Size					
less than 3cm	13	65.0	12	50	0.317
3cm or more	7	35.0	12	50	
Mechanism of injury					
Non-MVA	6	30.0	7	29.2	0.952
MVA	14	70.0	17	70.8	
Time of injury					
less than 4 Hours	13	65.0	17	70.8	0.679
4 Hours or more	7	35.0	7	29.2	

* The P-values for Chi-square for each variables showed there was no significant statistical enrolment difference.

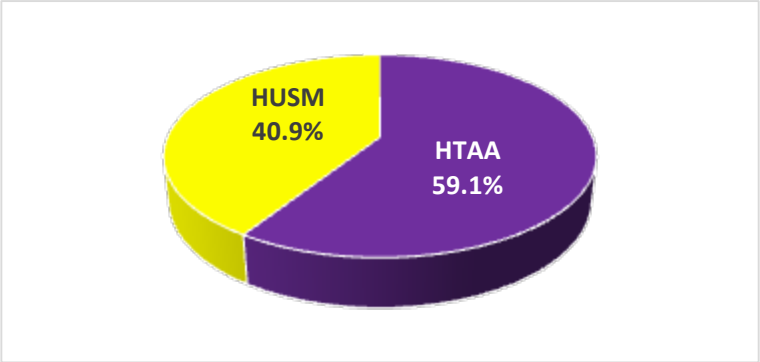


Figure 2: Distribution of patients according to Hospital (n=44)

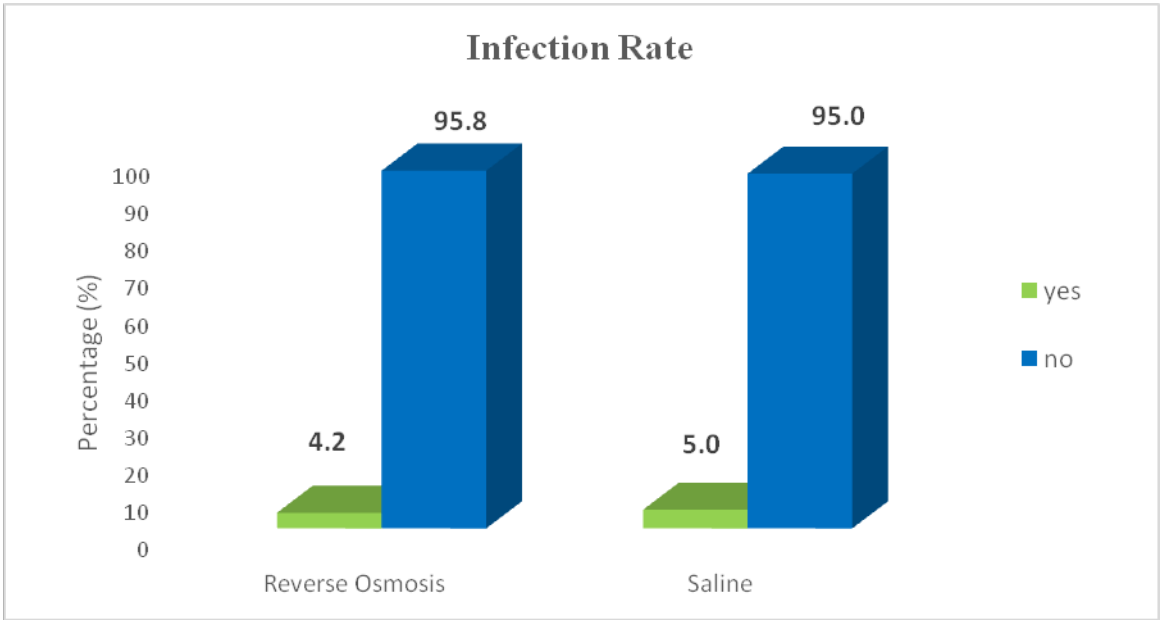


Figure 3: Infection rate for type of dressing (n=44)

Infection rate for sterile saline cleansing is 5% (95% CI -4.55%, 14.55%) and infection rate for RO cleansing is 4.17% (95% CI -3.83%, 12.17%). Comparison of infection in each group was shown in **Table 2**. No significant effect on type of cleansing agent on wound infection. Relative risk for RO water group was 0.834 (95% CI 0.056, 12.494) compare to saline group.

Table 2: Comparison of infection rate in both cleansing agent.

Type of agent	Infection		No infection		P value*
	N	(%)	N	(%)	
RO water	1	4.2	23	95.8	>0.95 (*NS)
Sterile Saline	1	5.0	19	95.0	

* P value for Fisher Exact Test

* NS – not significant, P > 0.95

Comparison of wound characteristics for wound infection was shown in **Table 3**. All wound characteristics showed no significant relation to wound infection. However the 2 infected wounds have similarities in all of variables. Both of them located at limbs, required suturing, sized of 3cm and more and presented to ED after 4 hours.

Table 3: Comparison of wound characteristic related to wound infection.

Variable	Infection		No infection		P value*
	n	(%)	n	(%)	
Site wound					
Head/neck	0	0.0	20	100	0.493
Limbs	2	8.3	22	91.7	
Suture					
Yes	2	6.3	30	93.8	0.524
No	0	0	12	100	
Size					
less than 3cm	0	0	25	100	0.181
3cm and more	2	4.5	42	95.5	
Mechanism of injury					
MVA	2	15.4	11	84.6	0.082
Non MVA	0	0	31	100	
Time injury					
less than 4Hours	0	0	30	100	0.096
4Hours or more	2	4.5	12	95.5	

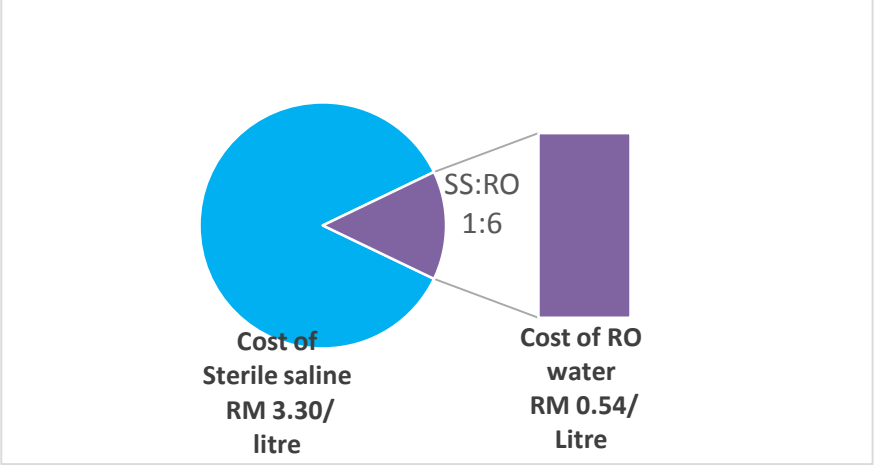


Figure 4: Ratio of cost of Sterile Saline to Reverse Osmosis water

DISCUSSION

Wound management is a very common encounter for emergency care personnel worldwide and it has changed significantly over the years. The most important aspect of wound management is wound cleansing or irrigation to prevent infection. There are three parts to successful wound cleansing: the technique, the choice of equipment and the cleansing agent (Trevelyan, 1996).

Wound infection in traumatic lacerations is the most common complication, occurring in 3% to 5% of cases (Tintinalli, 2011). Therefore, a proper method of decontamination before skin closure is vital to reduce wound infection rates. Clinicians and manufacturers have recommended various methods and cleansing agents for their supposed therapeutic value.

In this pilot study, an alternative cleansing solution to the currently popular sterile normal saline was being evaluated in term of infection rate and cost difference. Our results did not show any superiority of SS as an irrigant with infection rate of 5% in SS group and 4.7% in RO group. This finding had similar agreement with previous animal & human studies comparing saline and tap water, with results mostly showed no different or in some favours tap water in term of infection rate (Moscati *et al*, 2007; Bansal *et al*, 2002).

Tap water was not considered in this study since it is not of ‘drinkable’ quality in Malaysia. Interestingly, Nagoba *et al* (2015) concluded that it is still unsafe to use tap water for wound irrigation in developing countries where the quality of tap water is a questionable issue.

Reverse osmosis water was instead selected as it is easily available in the market, is cheaper than the saline and most importantly it is safe for human consumption. Theoretically RO water is hypotonic and has the risk of tissue damage due to cellular oedema and lysis, thus contribute to the wound infection. Although we did not examine the specimens to look for cell damage, our results did not show any significant infection rates in RO group.

While the difference in infection rate was small, RO water group shows slightly lower than the sterile saline group. However, the study needs larger sample size for statistically significant data and difference. A longer period of study with more centre involvement is also needed to improve the number and variety of subjects.

In term of wound locations, our data suggested higher proportion of wound infection occurring in the limbs (extremities) rather than head and neck region. Previous studies have shown similar trend and postulated that lower infection rate of the head & neck region due to rich of blood supply to these regions (Valente, 2003 ; Hollander,1998)

A few similarities of the two infected wounds have been noted: timing of injury to cleansing (7-9 hours), size of the wound (more than 5cm), patient's age (more than 50 years) and both wounds required suturing. These findings support the evidence from previous studies. In a study done by Angerås *et al.*, (1991), infected wounds were found to be significantly larger than uninfected ones. Torpy *et al.*, (2005) and Hollander *et a.l* (2001) highlighted that older and increasing age is one of the risk factor of infection in traumatic wounds.

The association of suture and wound infection has been studied mostly among surgical patients espcially post operatively. The presence of suture material is known to cause adverse effect on tissue condition and increase susceptibility to infection (Katz S *et al* 1981). Although there is a direct relationship between the time interval from injury to wound closure and the risk of subsequent infection, the length of this period is highly variable. A study conducted on hand and forearm lacerations found that closure within 4 hours had a lower infection rate than later closure. (Capellan and Hollander, 2003). The statement correlates with our results in which the two subjects with infected wounds presented to ED after 7-9 hours and have had suturing done for the wounds.

Cost management is an important factor as it has became a popular issue at national and international level. Undoubtedly, SS solution was costly than tap water, RO & stilled water (Ronald *et al*, 2007). For this trial, the cost of 1 Litre of RO water is RM 0.54 as compared to RM 3.30 (2015 Medical Catalogue HTAA & HUSM) for sterile saline of same volume. As the amount of fluid used for irrigation has been fixed at 1Litre in this study, for each patient irrigated with RO water, RM 2.76 can be saved. (Recommended volume of fluid = 60ml / centimetre wound length or minimum of 200ml per irrigation)(Tintinalli, 2011). Cumulatively, for 20 patients who use 1L of RO water instead sterile saline for wound cleansing, RM 55.20 can be saved.

Our study has some important differences from previous studies. Notably, we used RO water as alternative to tap water for irrigation to compare with normal saline. As mentioned before, the tap water quality in developing countries is still poor and not at par with the developed countries. Most of the study review and recommendation are from developed countries which their water quality is excellent and is as good as like mineral water with least or no

contamination with pathogenic microorganism. For developing countries some authors suggested to use pathogen-free boiled water, distilled or mineral water for wound cleansing (Nagoba, 2015) which is better and safer option for wound irrigation.

With regards to our finding, RO water can be added as one of the option for wound cleansing in developing countries. Another distinguishing factor is that our study took place at multiple centres. The subjects were selected from tertiary hospital in two different cities.

LIMITATIONS

There were several limitations to this pilot study. First and most importantly the sample size. The small sample size contributed to insufficient power and insignificant results thus limited further analysis of variables. Secondly, as this is the first trial of RO water being used for wound irrigation, there is no data to compare with.

In term of selecting the patients, as the researcher was not all the time available in ED, there was possibility of selection bias in which patients may not be enrolled consecutively or the treating doctors may opt not to select the eligible patients.

In this study the outcome of wound infection was measured only using subjective indicators – for example redness, stitch abscess, fever and presence of gross exudates. There is no objective measurement like bacterial counts or wound cultures to support or confirm the criteria.

A final limitation was regarding pressure used for irrigation. We did not exactly measure the pressure-irrigation during procedure. However, previous study have shown with 35-65 ml syringe and 19-needle catheter can achieve pressure of 25-35 psi for irrigation which is able to provide sufficient pressure for adequate wound irrigation (Singer, 2008)

CONCLUSION

Equivalent rates of wound infection were found using either irrigant solution. However, RO water wound cleansing is more cost-effective and appears to be equally safe and efficacious. Therefore, RO should be considered as a reasonable alternative to saline for wound cleansing in ED.

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Appendix 1 : Data Collection Form

A Pilot Study of Traumatic Laceration Wound Cleansing in Emergency Department : Sterile Saline versus Reverse Osmosis water

(please tick one)

☐ **CONTROL GROUP: STERILE SALINE**

☐ **TEST GROUP: REVERSE OSMOSIS WATER**

Demographic Data

ID no (I/C or Passport) : ..... Study No. : .....

Date of birth : ..../...../..... Age : ..... Gender : * Male / Female

Occupation : .....

Contact Number : .....

Nearest Health Clinic/Hospital : .....

Type/mechanism of trauma : .....

(e.g Motor Vehicle Accident / fall / sports injury / assaulted etc)

Date & Time of trauma : .....

Date & Time of dressing : .....

Site of laceration wound : .....

(scalp/face/chest/abdomen/back/hand/forearm/elbow/arm/thigh/knee/leg/ankle/foot)

Size of laceration wound: ..... cm

Any suturing done? : YES / NO.

Checklist (Exclusion criteria):

- Below 18 year old.
- Any underlying immunocompromising illness ? (eg, Diabetes, Chronic Kidney Disease(CKD), chronic alcoholism, primary immune disorder, steroid use or chemotherapy)
- Any current use of antibiotics/concurrent infection?
- Is it a puncture or bite wound?
- Any complicated wounds? (e.g. underlying tendon or bone involvement)
- Any associated major injury? (e.g Severe Head Injury/ Chest or Intraabdominal injury)
- Is the wound more than 9 hours old?

Wound evaluation

Criteria	**DAY 5**	**DAY 14**
• Stitch abscess	Yes / No	Yes / No
• Erythema/redness	Yes / No	Yes / No
• Gross exudates/ discharge	Yes / No	Yes / No
• Fever ⩾38°C	Yes / No	Yes / No

Dressing performed by: .....
(Sign & Chop)

Reporter Name: .....

Reporter Signature: ..... Date : .....

Appendix 2 : consent forms Malay and English

MAKLUMAT KAJIAN

Tajuk Kajian : **Kajian Pembersihan Luka Trauma di Jabatan Kecemasan : Perbandingan antara Air 'Saline' dan Air '*Reverse Osmosis(RO)*' di Hospital Universiti Sains Malaysia, Kelantan dan Hospital Tengku Ampuan Afzan, Pahang**

Nama Penyelidik : **Dr Anas Amri Bin Hashim, MPM 48219**

Nama Penyelia : **Dr Mohd Hashairi Bin Haji Fauzi, MPM 39626**

PENGENALAN

Anda dipelawa untuk menyertai satu kajian penyelidikan secara sukarela berkenaan pembersihan luka trauma di Jabatan Kecemasan. Kajian ini akan mengkaji perbezaan kesan pembersihan luka yang menggunakan dua jenis bahan cecair iaitu air 'Saline' (cecair yang biasanya digunakan) dan air 'Reverse Osmosis(RO)'(cecair bagi eksperimental). Air RO merupakan air yang dihasilkan daripada teknik penyucian air melalui membran separa tapis. Ia bersifat jernih dan bebas daripada sebarang bau. Proses RO menyerap bahan kimia toksik dan menjadikannya air yang bole diminum. Melalui proses RO jugak, bahan-bahan tercemar yang menyebabkan rasa yang tidak sedap akan ditapis.Kedua-dua air Saline dan air RO adalah bersih dan 'sterile'. Kajian ini tidak melibatkan mana-mana penaja. Kajian ini melibatkan peserta seramai 40 orang.

TUJUAN KAJIAN

Kajian ini bertujuan adalah untuk menentukan perbezaan kadar jangkitan luka trauma selepas dibersihkan menggunakan air 'Saline' atau air Reverse Osmosis. Selain itu, perbezaan kos antara dua cecair pembersih luka ini juga akan dikaji.

KELAYAKAN PENYERTAAN

Beberapa syarat-syarat kelayakan untuk menyertai kajian ini adalah:

- Anda mestilah berumur 18 tahun dan ke atas dan mendapatkan rawatan di Jabatan Kecemasan Hospital Universiti Sains Malaysia atau Hospital Tengku Ampuan Afzan.
- Anda mesti memberikan/menyatakan nombor telefon yang boleh dihubungi bagi tujuan pemeriksaan susulan.
- Anda TIDAK menghidap penyakit-penyakit seperti Diabetes, Penyakit Buah Pinggang, Pengambilan alcohol yang kronik, penggunaan steroid atau sedang menjalani Kemoterapi.
- Anda TIDAK mengambil antibiotik/mengidap sebarang jangkitan lain semasa kajian
- Luka anda BUKAN luka yang dalam (melibatkan tendon/tulang) dan luka disebabkan gigitan haiwan/manusia (*bite wound)*
- Luka yang TIDAK lebih dari 9 jam.
- TIDAK mengalami kecederaan major yang lain seperti pendarahan dalam kepala/otak, kecederaan dalaman di dada/thorak atau abdomen yang memerlukan penggunaan antibiotik atau pembedahan.

PROSEDUR KAJIAN

Sekiranya anda bersetuju dan memenuhi syarat-syarat kelayakan yang telah ditetapkan, maka doktor bersama Penolong Pegawai Perubatan/Jururawat Terlatih yang bertugas pada waktu berkenaan akan mengambil borang data kajian yang telah menetapkan anda kepada kumpulan yang lukanya akan dibersihkan menggunakan air 'saline' ATAU kumpulan yang lukanya akan dibersihkan menggunakan air 'Reverse Osmosis'. Tetapan untuk kumpulan ini ada berdasarkan teknik rawak blok (block randomisation). Teknik rawak blok ini adalah bersaiz 4 dimana kombinasi 2 S (saline water) dan 2 R (RO water) akan digunakan. Terdapat 6 kombinasi blok yang mungkin (1 = SSRR, 2 = SRSR, 3=SRRS, 4=RSSR, 5=RSRS, 6= RRSS). Kemudian, blok-blok ini akan dirawakkan lagi menggunakan komputer. Anda juga tidak akan dimaklumkan mengenai cecair yang akan digunakan untuk anda bagi mengelakkan potensi reaksi dan respon yang '*bias*'.

Teknik dan tatacara pembersihan luka adalah sama dan berlandaskan prinsip pembersihan luka trauma seperti ditetapkan oleh WHO. Pembersihan luka akan dilakukan oleh pembantu pegawai perubatan/jururawat terlatih yang ditugaskan khusus. 1 liter air saline atau RO akan digunakan. Sampel akan dimasukkan dalam bekas yang sterile contohnya – *pot/kidney dish* . irigasi luka akan dilakukan menggunakan 'srynge' dan *'branula catheter'* . Bagi mengawal punca jangkitan, 'sterile gloves', Personal Protective Equipment/wear dan sterile set pembersihan luka akan digunakan.Pesakit juga akan disaring berdasarkan kriteria kajian. Selepas luka dibersihkan, anda akan dibenarkan pulang. Anda akan diminta untuk hadir kembali ke hospital untuk membolehkan luka anda dinilai semula oleh penyelidik/doktor pada hari ke 5 dan hari ke 14 selepas trauma. Tanda-tanda jangkitan luka akan diterangkan kepada pesakit sebelum pesakit dibenarkan pulang. Tempoh jangkaan penglibatan anda dalam kajian ini adalah selama 14 hari.

RISIKO

Risiko yang mungkin anda alami dalam kajian ini adalah sama seperti risiko setiap luka trauma (selain daripada luka-luka yang dalam atau rumit) iaitu risiko jangkitan pada luka anda yang boleh menyebabkan proses penyembuhan luka yang lebih panjang dan kesakitan pada luka. Sekiranya didapati luka anda mempunyai tanda-tanda jangkitan atau mempunyai komplikasi, rawatan lanjut seperti antibiotik atau pembedahan kecil akan diberikan.

PENYERTAAN DALAM KAJIAN

Penyertaan anda dalam kajian ini adalah secara sukarela. Anda berhak menolak untuk menyertai kajian ini atau anda boleh menamatkan penyertaan anda pada bila-bila masa, tanpa sebarang hukuman dan rawatan kesihatan anda akan diteruskan seperti sepatutnya. Penyertaan anda juga mungkin boleh diberhentikan oleh doktor yang terlibat dalam kajian ini tanpa persetujuan anda sekiranya risiko perubatan dikhuatiri berlaku. Jika anda berhenti menyertai kajian ini, ia tidak akan memberi kesan atau menghalang anda daripada rawatan dan servis yang ditentukan.

MANFAAT YANG MUNGKIN DIPEROLEHI (MANFAAT TERHADAP INDIVIDU, MASYARAKAT, UNIVERSITI)

Hasil atau maklumat kajian ini diharapkan, dapat memberi manfaat kepada para pesakit, hospital seterusnya masyarakat pada masa hadapan khususnya dalam bidang berkaitan rawatan luka trauma.Prosedur kajian ini akan diberikan kepada anda tanpa kos (kecuali bayaran pendaftaran hospital seperti yang tertakluk kepada pihak hospital). Tiada imbuhan kusus kepada peserta kajian.

PERSOALAN

Sekiranya anda mempunyai soalan mengenai prosedur kajian ini atau hak-hak anda, sila hubungi;

Dr Anas Amri Bin Hashim MPM 48219

Jabatan Perubatan Kecemasan dan Trauma

Pusat Pengajian Sains Perubatan, USM.

Tel. No: 09-767 3219 / 012-4516042

Email: dranasamri@gmail.com

Sekiranya anda mempunyai sebarang soalan berkaitan kelulusan etika, sila hubungi;

Medical Research Ethics Committee (MREC)

Ministry of Health Malaysia,

c/o Institute for Health Management,

JalanRumahSakit, Bangsar, 59000 Kuala Lumpur.

Phone: 03-2282 9082 / 03-2282 9085 / 03-2287 4032, Fax: 03 - 2287 4030
Email: nihsec@nih.gov.my
URL: http://www.nih.gov.my

ATAU

En Mohd Bazlan Hafidz Mukrim

Setiausaha Jawatankuasa Etika Penyelidikan (Manusia) USM

Pusat Inisiatif Penyelidikan -Sains Klinikal & Kesihatan USM.

No. Tel: 09-767 2355 / 09-767 2352

Email: jepem.usm@gmail.com

KERAHSIAAN

Maklumat perubatan anda akan dirahsiakan oleh doktor dan kakitangan kajian. Ianya tidak akan dedahkan secara umum melainkan jika ia dikehendaki oleh undang-undang.

Data yang diperolehi dari kajian yang tidak mengenalpasti anda secara perseorangan mungkin akan diterbitkan untuk tujuan memberi pengetahuan baru.

Borang jawapan anda yang asal mungkin akan dilihat oleh pihak penyelidik, Lembaga Etika untuk kajian ini dan pihak berkuasa regulatori untuk tujuan mengesahkan prosedur dan/atau data kajian klinikal. Maklumat yang diperoleh dari borang jawapan anda mungkin akan disimpan dan diproses dengan komputer.

Anda akan dimaklumkan mengenai keputusan kajian sekiranya diminta.

Dengan menandatangani borang persetujuan ini, anda membenarkan penyelidikan, penyimpanan dan pemindahan maklumat seperti yang dihuraikan di atas.

TANDATANGAN

Untuk dimasukkan ke dalam kajian ini, anda atau wakil sah anda mesti menandatangani serta mencatatkan tarikh halaman tandatangan [lihat LAMPIRAN 1].

Borang Keizinan Subjek

(Halaman Tandatangan)

Tajuk Kajian : **Kajian Pembersihan Luka Trauma di Jabatan Kecemasan : Perbandingan antara Air 'Saline' dan Air 'Reverse Osmosis(RO)' di Hospital Universiti Sains Malaysia, Kelantan dan Hospital Tengku Ampuan Afzan, Pahang**

Nama Penyelidik : **Dr Anas Amri Bin Hashim, MPM 48219**

Nama Penyelia : **Dr Mohd Hashairi Bin Haji Fauzi, MPM 39626**

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini. Dengan menandatangani mukasurat ini, saya mengesahkan yang berikut:

- Saya telah membaca semua maklumat dalam Borang Maklumat dan Keizinan Pesakit ini termasuk apa-apa maklumat berkaitan risiko yang ada dalam kajian dan saya telah pun diberi masa yang mencukupi untuk mempertimbangkan maklumat tersebut.
- Semua soalan-soalan saya telah dijawab dengan memuaskan.
- Saya, secara sukarela, bersetuju menyertai kajian penyelidikan ini, mematuhi segala prosedur kajian dan memberi maklumat yang diperlukan kepada doktor, para jururawat dan juga kakitangan lain yang berkaitan apabila diminta.
- Saya boleh menamatkan penyertaan saya dalam kajian ini pada bila-bila masa.
- Saya telah pun menerima satu salinan Borang Maklumat dan Keizinan Pesakit untuk simpanan peribadi saya.

_____

Nama Subjek

_____

No. Kad Pengenalan Subjek (Baru)

_____ _____

Tandatangan Subjek **Tarikh** (dd/mm/yy)

_____

Tandatangan Wakil Sah

_____ _____

Nama & Tandatangan Individu yang Mengendalikan Perbincangan Keizinan (SELAIN DARIPADA PENYELIDIK)

Tarikh (dd/mm/yy)

_____ _____

Nama Saksi dan Tandatangan **Tarikh(**dd/mm/yy)

Borang Keizinan bagi Penerbitan Bahan yang berkaitan dengan Pesakit/ Subjek

(Halaman Tandatangan)

Tajuk Kajian : **Kajian Pembersihan Luka Trauma di Jabatan Kecemasan : Perbandingan antara Air 'Saline' dan Air 'Reverse Osmosis(RO)' di Hospital Universiti Sains Malaysia, Kelantan dan Hospital Tengku Ampuan Afzan, Pahang**

Nama Penyelidik : **Dr Anas Amri Bin Hashim, MPM 48219**

Nama Penyelia : **Dr Mohd Hashairi Bin Haji Fauzi, MPM 39626**

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini.

Dengan menandatangani mukasurat ini, saya memahami yang berikut:

- Bahan yang akan diterbitkan tanpa dilampirkan dengan nama saya dan setiap percubaan yang akan dibuat untuk memastikan ketanpanamaan saya. Saya memahami, walaubagaimanapun, ketanpanamaan yang sempurna tidak dapat dijamin. Kemungkinan sesiapa yang menjaga saya di hospital atau saudara dapat mengenali saya.
- Bahan yang akan diterbitkan dalam penerbitan mingguan/bulanan/dwibulanan/suku tahunan/dwi tahunan merupakan satu penyebaran yang luas dan tersebar ke seluruh dunia. Kebanyakan penerbitan ini akan tersebar kepada doktor-doktor dan juga bukan doktor termasuk ahli sains dan ahli jurnal.
- Bahan tersebut juga akan dilampirkan pada laman web jurnal di seluruh dunia. Sesetengah laman web ini bebas dikunjungi oleh semua orang.
- Bahan tersebut juga akan digunakan sebagai penerbitan tempatan dan disampaikan oleh ramai doktor dan ahli sains di seluruh dunia.
- Bahan tersebut juga akan digunakan sebagai penerbitan buku oleh penerbit jurnal.
- Bahan tersebut tidak akan digunakan untuk pengiklanan ataupun bahan untuk membungkus.

Saya juga memberi keizinan bahawa bahan tersebut boleh digunakan sebagai penerbitan lain yang diminta oleh penerbit dengan kriteria berikut:

- Bahan tersebut tidak akan digunakan untuk pengiklanan atau bahan untuk membungkus.
- Bahan tersebut tidak akan digunakan di luar konteks – contohnya: Gambar tidak akan digunakan untuk menggambarkan sesuatu artikel yang tidak berkaitan dengan subjek dalam foto tersebut.

Nama Pesakit (Dicetak atau Ditaip) Nama Singkatan atauNo. Pesakit

No. Kad Pengenalan Pesakit T/tangan Pesakit Tarikh (dd/MM/yy)

Nama & Tandatangan Individuyang MengendalikanTarikh (dd/MM/yy)

Perbincangan Keizinan (Dicetak atau Ditaip)(SELAIN DARIPADA PENYELIDIK)

Nota: i) Semua subjek/pesakit yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

RESEARCH INFORMATION

Research Title: **A Pilot Study of Traumatic Laceration Wound Cleansing in Emergency Department :Saline versus Reversed Osmosis (RO) water, in Hospital Universiti Sains Malaysia(HUSM), Kelantan and Hospital Tengku Ampuan Afzan(HTAA), Pahang**

Researcher's Name : **Dr Anas Amri Bin Hashim, MPM 48219**

Supervisor's Name : **Dr Mohd Hashairi Bin Haji Fauzi, MPM 39626**

INTRODUCTION

You are invited to take part voluntarily in a research study on traumatic laceration wound cleansing in Emergency Department(ED), comparing the efffect of dressing using saline water(standard agent) versus Reverse Osmosis(RO) water (experimental agent).Reverse Osmosis(RO) is water purification technology that uses a semipermeable membrane. It is free from unwanted odors or odorless and it's also colorless. It does not contain minerals that are dissolved unlike other water produced by different filtration systems. RO absorbs toxic chemicals making the water output fit for human consumption.Throughout the process of RO, contaminant that makes the water taste unpleasant is removed. Both saline water and RO water are sterile water. There's no sponsor involves in this study. Targetted number of participant is 40.

PURPOSE OF THE STUDY

The main purpose of this study is to determine the rate of infection in uncomplicated traumatic laceration wounds, after cleansing with saline water and RO water. The cost difference between the two solutions will also be analysed.

QUALIFICATION TO PARTICIPATE

Requirement criteria to participate in this study are:

- 18 years and older of age, who presented to the ED with an uncomplicated soft tissue laceration wounds.
- Patients had to provide a telephone number for follow-up purpose.
- NO underlying immunocompromising illness (eg, Diabetes, Kidney disease, chronic alcoholism, primary immune disorder, steroid use or chemotherapy),
- NO current use of antibiotics,
- Wound is NOT a puncture or bite wound,
- Wound with NO underlying tendon or bone involvement

- Wounds more than 9 hours old.
- NO concurrent major injuries which may require use of antibiotics or surgery e.g Severe Head Injury, internal injury e.g Chest/Intraabdominal Injury.

STUDY PROCEDURES

If you agreed to participate in this study, the doctor incharge together with the assigned Medical Assistant or Trained Staff Nurse will take the data collecting form, which has already been assigned into 2 different group by randomization method. In this study, block randomization system will be used, in which data collection forms will be arrange in block of interventional and control group so that in a given time, the sample size of both group will be comparable. Here, a block size of 4 is chosen. Balanced combinations with 2 S (Saline Water) and 2 R (RO water) subjects are calculated as 6 combination blocks (1= SSRR, 2= SRSR, 3= SRRS, 4= RSSR, 5= SRSR, 6= RRSS). Then sequence of block will be randomly selected and arranged by computer.You can either be in the group of patients that will undergo dressing with saline water (S) OR group that will undergo dressing with Reverse Osmosis water (R). You will also be blinded (not knowing wihich agent you receive) in order to avoid any potential biased reactions or responses.

Dressing will be conducted by an assigned medical assistant/staff nurse appointed for Trauma Wound management. 1 litre of saline water or RO water will be used for irrigation of the wound. Each sample will be put into a steriled container e.g pot/kidney dish. Then irrigation will be done using syringe and branula catheter. Dressing will be done as per standard of wound dressing recommended by WHO. In order to control source of infection, dressor will be wearing sterile gloves, approriate personal protective equipment/wear and using steriled dressing set. All possible source of infection as per exclusion criteria will be screened beforehand.

After dressing, you will be allowed to go home with advices given by the doctor regarding signs and symptoms of wound infection. You will be asked to return to Emergency Department for wound evaluation on day 5 & 14 post trauma. Estimated duration of involvement in this study is 14 days.

RISKS

As for other uncomplicated traumatic wounds, there will be risk of wound infection to occur, which may delay the wound healing and cause increase in pain. In case of any sign or symptom of infection or study related injury present, immediate treatment, e.g antibiotics / surgical debridement will be intiated.

PARTICIPATION IN THE STUDY

Your taking part in this study is entirely voluntary. You may refuse to take part in the study without giving any significant reason. Your participation also may be stopped by the study doctor without your consent. Your refusal or withdrawal from this study would not affect medical services entitled for you.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]

There is no direct benefit to the participant.We hope that the outcome and informations gained from this research will benefit the future patients, health institutions and society.Dressing procedures are not chargeable. You may only need to pay the usual hospital registration fee (depending on Hospital's Regulations)

QUESTIONS

If you have any question about this study or your rights, please contact;

Dr Anas Amri Bin Hashim MPM 48219

Jabatan Perubatan Kecemasan dan Trauma

Pusat Pengajian Sains Perubatan, USM.

Tel. No: 09-767 3219 / 012-4516042

Email: dranasamri@gmail.com

If you have any questions regarding the Ethical Approval, please contact;

Medical Research Ethics Committee (MREC)

Ministry of Health Malaysia, c/o Institute for Health Management, JalanRumahSakit, Bangsar, 59000 Kuala Lumpur.

Phone: 03-2282 9082 / 03-2282 9085 / 03-2287 4032 Fax: 03 - 2287 4030
Email: nihsec@nih.gov.my
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OR

En Mohd Bazlan Hafidz Mukrim

Setiausaha Jawatankuasa Etika Penyelidikan (Manusia) USM

Pusat Inisiatif Penyelidikan -Sains Klinikal & Kesihatan USM.

No. Tel: 09-767 2355 / 09-767 2352

Email: jepem.usm@gmail.com

CONFIDENTIALITY

Your personal information and answers in this study will be kept confidential by the study doctor and staff and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually may be published for knowledge purposes.

You may be informed of the findings of the study upon your request.

Your answer form may be reviewed by Ethical Review Board for this study and regulatory authorities for the purpose of verifying clinical trial procedures and/or data. Information gained from your form may also be held and processed on a computer.

By signing this consent form, you authorize the review, storage, transfer and publication of the data described above.

SIGNATURES

To be entered into the study, you or a legal representative must sign and data the signature page [ATTACHMENT 1]

Subject Information and Consent Form

(Signature Page)

Research Title: **A Pilot Study of Traumatic Laceration Wound Cleansing in Emergency Department : Saline versus Reversed Osmosis (RO) water, in Hospital Universiti Sains Malaysia(HUSM), Kelantan and Hospital Tengku Ampuan Afzan(HTAA), Pahang**

Researcher's Name : **Dr Anas Amri Bin Hashim, MPM 48219**

Supervisor's Name : **Dr Mohd Hashairi bin Haji Fauzi, MPM 39626**

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form including any information regarding the risk in this study and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Patient Information and Consent Form to keep for myself.

_____

Subject Name

_____

Subject I.C No.

_____ _____

Signature of Subject Date (dd/mm/yy)

_____

Signature of Legal Representative

Name of Individual

Conducting Consent Discussion (Print or Type)

(OTHER THAN RESEARCHER)

Signature of Individual

Date (dd/mm/yy)

Conducting Consent Discussion

Name & Signature of Witness

Date (dd/MM/yy)

Patient's Material Publication Consent Form

Signature Page

Research Title: **A Pilot Study of Traumatic Laceration Wound Cleansing in Emergency Department : Saline versus Reversed Osmosis (RO) water, in Hospital Universiti Sains Malaysia(HUSM), Kelantan and Hospital Tengku Ampuan Afzan(HTAA), Pahang**

Researcher's Name : **Dr Anas Amri Bin Hashim, MPM 48219**

Supervisor's Name : **Dr Mohd Hashairi bin Haji Fauzi, MPM 39626**

To become a part this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalist worldwide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors worldwide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
- The materials will not be used as advertisement purposes or as packaging materials.
- The materials will not be used out of contex – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

Patient Name (Print or type)

Patient InitialsorNumber

Patient I.C No.	Patient's Signature	Date (dd/MM/yy)

Name and Signature of Individual	Date (dd/MM/yy)

Conducting Consent Discussion

(OTHER THAN RESEARCHER)

Note: i) All subject/patients who are involved in this study will not be covered by insurance

Appendix 3 : Approval Letter (Ministry of Health)

JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(Medical Research & Ethics Committee)
KEMENTERIAN KESIHATAN MALAYSIA
d/a Institut Pengurusan Kesihatan
Jalan Rumah Sakit, Bangsar
59000 Kuala Lumpur

Tel : 03 2282 0491
Faks : 03 2282 8072 / 03 2282 0015

Ref : (17)KKM/NIHSEC/ P14-945
Date : 9 Januari 2015

NMRR-14-955-21527 (IIR)
A Pilot Study of Traumatic Laceration Wound Dressing in Emergency Department(ED): Saline versus Reverse Osmosis(RO) Water in Hospital Universiti Sains Malaysia(HUSM) and Hospital Tengku Ampuan Afzan(HTAA), Kuantan

Principal Investigator/s : Dr Anas Amri Bin Hashim
Hospital Tengku Ampuan Afzan, Pahang Darul Makmur

Documents received and reviewed with reference to the above study:

1. Study Proposal version 2 dated 31-12-2014
2. Patient information sheet (English) & Informed Consent Form (English) version 2 dated 31-12-2014
3. Patient information sheet (Malay) & Informed Consent Form (Malay) version 2 dated 31-12-2014
4. Study Clinical Report Form version1 dated 21-08-2014
5. Investigator's CV for
   Dr Anas Amri Bin Hashim

Please note that the approval is valid until 9 Januari 2016. To renew the approval, a completed '**Continuing Review Form**' has to be submitted to MREC at least 2 months before the expiry of the approval. You are required to report occurrence of **all serious** and **unexpected adverse events** (if relevant) and a **Study Final Report** upon study completion to the MREC. The required forms can be obtained from the MREC website (**http://www.nih.gov.my/mrec**).

Please take note that the reference number for this letter must be stated in all correspondence related to this study to facilitate the process.

Comments (if any):

Project Sites: Hospital Tengku Ampuan Afzan

Decision by Medical Research & Ethics Committee:
(√) Approved
( ) Disapproved

Date of Approval : 9 Januari 2015

DATO' DR CHANG KIAN MENG
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia

Appendix 4 : Approval Letter (USM)

UNIVERSITI SAINS MALAYSIA

Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM)
Human Research Ethics Committee USM (HREC)

Universiti Sains Malaysia
Kampus Kesihatan,
16150 Kubang Kerian,
Kelantan. Malaysia.
T: 609 - 767 3000 *samb.* 2354/2
F: 609 - 767 2351
E: jepem@usm.my
www.jepem.kk.usm.my

30th September 2014

Dr. Anas Amri Hashim o/2-45/6042
Department of Emergency Medicine
School of Medical Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

JEPeM Code : USM/JEPeM/140232
Protocol Title : A Pilot Study of Traumatic Laceration Wound Dressing in Emergency Department: Saline Versus Reverse Osmosis (RO) Water in Hospital USM, Kelantan and Hospital Tengku Ampuan Afzan, Pahang.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/140232**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid until **September 2015.**

The following documents have been approved for use in the study.

1. Research Proposal

In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:

1. Patient Information Sheet and Consent Form (English version)
2. Patient Information Sheet and Consent Form (Malay version)
3. Data Collection Form

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:

1. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2014: Study Protocol Amendment Submission Form.**
2. Reports of adverse events (if any) including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2014: Adverse Events Report.**
3. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2014.**
4. Any event which may have ethical significance.
5. Any information which is needed by the JEPeM-USM to do ongoing review.
6. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2014: Final Report Form.**
7. Application for renewal of ethical clearance 90 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2014: Continuing Review Application Form.**

Please note that forms may be downloaded from the JEPeM-USM website: **www.jepem.kk.usm.my**

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with International Conference on Harmonization–Guidelines for Good Clinical Practice (ICH-GCP) guidelines and Declaration of Helsinki.

Thank you.

"ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

PROF. DR. HANS AMIN VAN ROSTENBERGHE
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia