

**2 YEARS AUDIT OF LAPAROSCOPIC
CHOLECYSTECTOMY PERFORMED IN HOSPITAL
USM AND FACTORS RELATED TO CONVERSION**

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ii. ABSTRAK IN BAHASA MALAYSIA

Latar belakang:

Kaedah rawatan piawaian emas bagi penyakit batu hempedu adalah kaedah pembedahan laparoskopik yang mana telah menggantikan kaedah pembedahan terbuka. Walaubagaimanapun, sebanyak 2-15% kes laparoskopik perlu ditukar kepada cara pembedahan terbuka kerana beberapa sebab tapi harus diingatkan bahawa penukaran ini bukanlah satu kegagalan atau komplikasi daripada pembedahan tetapi ianya untuk mengelakkan daripada komplikasi dan menjaga keselamatan pesakit.

Objektif:

Tujuan kajian ini adalah untuk menentukan kadar penukaran pembedahan laparoskopik kepada pembedahan secara terbuka di Hospital Universiti Sains Malaysia dan mengaitkan penukaran ini kepada demografik dan juga faktorisiko pesakit, iaitu nilai ALT, ALP dan WCC pra-pembedahan, ketebalan dinding pundi hempedu berdasarkan imej ultrabunyi, batu pundi hempedu dan laporan histopatologi.

Metodologi:

Ini adalah kajian retrospektif pesakit yang menjalani pembedahan pembuangan pundi hempedu secara laparoskopik di Hospital Universiti Sains Malaysia dari Oktober 2013 sehingga Disember 2015. Saiz sampel telah dikira dengan formula nisbah berseorangan dengan kadar keciciran sebanyak 20%. Pesakit berumur 18 tahun ke atas yang telah menjalani pembedahan pembuangan pundi hempedu secara laparoskopik di Hospital Universiti Sains Malaysia pada tempoh kajian di dalam kajian ini dimasukkan ke dalam kajian. Pengecualian pesakit di dalam kajian ini yang berumur kurang daripada 18 tahun, kes disyaki atau sah kanser, data rekod yang tidak lengkap, pembda

han kecemasan dan pembedahan pembuangan pundi hempedu secara dan pembedahan lain dilakukan bersama pada masa yang sama. Data pesakit dikumpulkan daripada rekod dan dianalisis menggunakan perisian SPSS. Analisis Univariat, ujian Chi-square dan analisis multivariat digunakan untuk logistik regresi berganda di mana nilai $p < 0.05$ adalah nilai perbezaan statistik yang ketara.

Keputusan kajian:

Jumlah pesakit yang terlibat adalah seramai 122 orang. Kadar penukaran daripada pembedahan laparoskopik kepada pembedahan terbuka adalah 11.5% (14 orang). Purata umur pesakit dalam kajian ini adalah 50.4 tahun di mana kebanyakan adalah pesakit wanita (70.5%) dan dari bangsa Melayu (91.8%). Kesemua pesakit dibahagikan kepada 2 kumpulan (laparoskopik dan pembedahan laparoskopik bertukar kepada pembedahan terbuka) dan analisis statistik seterusnya dilakukan. Ujian T bebas telah digunakan untuk membandingkan purata angka boleh ubah dan menunjukkan perubahan tidak ketara pada umur ($p=0.165$), WCC pra-pembedahan ($p=0.725$), ALP ($p=0.078$), ALT ($p=0.176$). Analisis univariat berdasarkan logistik regresi ringkas dan logistik regresi berganda digunakan dan menunjukkan ketebalan dinding pundi hempedu >4 mm adalah nilai yang ketara bagi faktor risiko penukaran pembedahan laparoskopik kepada pembedahan pembuangan pundi hempedu secara terbuka dengan nilai $p= 0.007$. pemboleh ubah yang lain tidak memberikan nilai yang ketara. Akhirnya, kawasan di bawah lengkungan kriteria penerimaan operasi (ROC) adalah 0.678 (95% CI; 0.52, 0.84) menandakan kuasa perbezaan yang memuaskan.

Kesimpulan:

Kajian ini menunjukkan kadar penukaran pembedahan pembuangan pundi hempedu laparoskopik di Hospital Universiti Sains Malaysia adalah 11.5%, iaitu di dalam lingkungan boleh diterima 2-15%.

Tambahan lagi, berdasarkan analisis logistik regresi berganda, ketebalan dinding pundi hempedu >4 mm pada gam bar ultrabunyi sebelum pembedahan adalah satu-satunya faktor risiko ketara dari segi statistik untuk penukaran laparoskopik kepada pembedahan terbuka untuk pembuangan pundi hempedu (nilai p 0.007, OR 0.21, 95% CI: 0.07, 0.65).

Introduction:

The gold standard for treatment of symptomatic gallstone disease is laparoscopic cholecystectomy which has nowadays replaced open surgery. However around 2-15% of the laparoscopic cases need to be converted to open cholecystectomy for various reasons but it should be noted that conversion to open is neither a failure nor a complication of the surgery but it is just to prevent further complication and for the safety of the patient.

Objectives:

This study aimed to report number of cases of laparoscopic cholecystectomy performed within 2 years in Hospital Universiti Sains Malaysia, determine the conversion rate and associate this conversion to demographics and patient risk factors which were preoperative ALT, ALP, WCC, ultrasound findings of gallbladder wall thickness, presence of gallstones and postoperative histopathological report.

Methods:

This was a retrospective study of patients undergoing elective laparoscopic cholecystectomy at Hospital Universiti Sains Malaysia from October 2013 to December 2015. The sample size was calculated using the single proportion formula with a drop out rate of 20%. Patients included in this study were those who were above 18 years of age undergoing elective laparoscopic cholecystectomy in Hospital Universiti Sains Malaysia within the time period mentioned above. The exclusion criteria were patients less than 18 years, cases suspected or confirmed malignancy, those with incomplete data records, emergency surgeries and finally those cases of laparoscopic

cholecystectomies combined with other surgeries under the same setting. The patients' data were collected from their records and statistical analysis was done using SPSS software. Univariate analysis, Chi-squared test and multivariate analysis for multiple logistic regression were done with a p-value of <0.05 considered as statistically significant.

Results:

The number of patients fulfilling the inclusion/exclusion criteria involved in this study was 122. The conversion rate of laparoscopic to open cholecystectomy was found to be 11.5%. The mean age of patients in this study was 50.4 years with majority females (70.5%) and of malay race (91.8%). The patients were divided into 2 groups (laparoscopic cholecystectomy and laparoscopic converted to open cholecystectomy) and further statistical analysis was performed. Independent T test used to compare the mean of numerical variables showed no statistically significant difference in age ($p = 0.165$), preoperative WCC ($p = 0.725$), ALP ($p = 0.078$), ALT ($p = 0.176$). Univariate analysis based on simple logistic regression and multiple logistic regression were also done and noted only gallbladder wall thickness > 4mm to be statistically significant risk factor for conversion of laparoscopic to open cholecystectomy with a p-value of 0.007. Other variables did not give statistically significant results. Ultimately the area under receiver operating characteristic (ROC) curve was 0.678 (95% CI; 0.52,0.84) which indicates satisfactory discriminating power.

Conclusion:

In this study, the conversion rate of laparoscopic to open cholecystectomy in Hospital Universiti Sains Malaysia for elective cases is 11.5% which is within the acceptable range of 2-15%. Furthermore, based on multiple logistic regression analysis, preoperative gallbladder wall thickness >4mm on ultrasound is the only statistically significant risk factor for conversion of laparoscopic to open cholecystectomy (p -value=0.007, adjusted OR=0.21, 95% CI: 0.07,0.65).

A. INTRODUCTION

Nowadays the gold standard for treatment of patients with symptomatic gallbladder disease is laparoscopic cholecystectomy which has replaced open surgery (Rosen M *et al.*, 2002; Cuschieri A *et al.*, 1991; Hollington P *et al.*, 1999; Ibrahim S *et al.*, 2006). The advantages of laparoscopic surgery are decreased postoperative pain, earlier oral intake, shorter hospital stay, early resumption of normal activity and improved cosmesis (Wei-Jie Z *et al.*, 2008; Harboe KM and Bardram L, 2011; Agrusa A *et al.*, 2014; Thami G *et al.*, 2015; Atta HM *et al.*, 2017). However 2-15% of laparoscopic cholecystectomies still need to be converted to open surgery for various reasons (Rosen M *et al.*, 2002). Numerous patient and disease-related factors, such as male gender, obesity, old age (> 65), prior abdominal surgery, acute cholecystitis, choledocholithiasis, and anomalous anatomy have been reported as significant risk factors for conversion to the open procedure (Livingston EH *et al.*, 2004; Liu CL *et al.*, 1996; Tang B and Cuschieri A, 2006; Ibrahim S *et al.*, 2006; Sujit VS *et al.*, 2010). Therefore identification of the preoperative parameters that are risk factors for possible conversion would be useful for both patients and surgeons (Ibrahim S *et al.*, 2006).

It is important to realise that the need for conversion to laparotomy is neither a failure nor a complication, but an attempt to avoid complication and ensure patient safety (Rosen M *et al.*, 2002; Sanabria JR *et al.*, 1994; Alponat A *et al.*, 1997). In preoperatively predicted conversion, early decision can be made by senior surgeon so as to avoid unnecessarily prolonging the surgery and to prevent complications (Gupta N *et al.*, 2013; Vivek MK *et al.*, 2014; Soltes M and Radoak J, 2014; Sugrue M *et al.*, 2015). Furthermore, hospital administrators can appropriately plan bed space for those patients having a high likelihood of conversion. In addition, the surgeon and operating team can organise an appropriate plan and arrange for hospital admission or ambulatory surgery with appropriate expenses (Rosen M *et al.*, 2002). The ability to accurately identify an individual

patient's risk for conversion based on preoperative information can result in more meaningful and accurate preoperative counselling, improved operating room scheduling and efficiency, stratification of risk for technical difficulty, and appropriate assignment of resident assistance, may improve patient safety by minimising time to conversion, and helps to identify patients in whom a planned open cholecystectomy is indicated (Jeremy ML *et al.*, 2007; Goyal V *et al.*, 2017).

i. LITERATURE REVIEW

Sujit Vijay Sakpal *et al* analysed retrospectively 2205 patients who underwent laparoscopic cholecystectomy in New Jersey, USA from May 2004 to October 2008. The conversion rate was noted to be 4.9% with most patients found to be males over 50[mean 66.1] years of age (Sujit VS *et al.*, 2010).

Salleh Ibrahim *et al* did a retrospective study for 1000 laparoscopic cholecystectomy patients in Changi General Hospital, Singapore from May 1998 to May 2004. The conversion rate was 11.5% and significant risk factors for conversion were male gender, advanced age (> 60 years), higher body weight > 65 kg, acute cholecystitis, previous upper abdominal surgery, junior surgeons, and diabetes associated with Hba1c > 6 (Ibrahim S *et al.*, 2006).

Wei-Jie Zhang *et al* performed a retrospective study in China involving 1265 candidates who underwent laparoscopic cholecystectomy (Wei-Jie Z *et al.*, 2008). Preoperative clinical, laboratory and radiographic parameters were analysed and the results showed 7.4% were converted to open surgery. Multivariate analysis identified male sex, with Murphy's sign positive, gall bladder wall thickness > 4 mm and previous upper abdominal surgery as independent predictors of conversion rate to laparotomy. Old age, male sex, body mass index (BMI) >30 kg/m², previous upper abdominal surgery, preoperative diagnosis of acute cholecystitis, gall bladder wall thickness,

positive Murphy's sign, high total white blood cell count and C-reactive protein level were significantly associated with conversion to open surgery (Wei-Jie Z *et al.*, 2008).

Ravindra Nidoni *et al* conducted a prospective study from October 2010 to October 2014 in India with 180 patients undergoing laparoscopic cholecystectomy. Results showed that 5.56 % of the cases were converted to open surgery and that total leucocyte count >11000, more than 2 previous attacks of cholecystitis, GB wall thickness of >3mm and pericholecystic collection were all statistically significant for predicting the difficult laparoscopic cholecystectomy and its conversion (Ravindra N *et al.*, 2015).

Volkan Genc *et al* studied retrospectively 5164 gallstones patients who required laparoscopic cholecystectomy in Ankara University of Turkey from May 1999 to June 2010 and noted that 3.16% of those cases needed to be converted to open cholecystectomy. The mean age for conversion was noted to be 52.04 years and male gender was the only statistically significant risk factor for conversion in this study (Volkan G *et al.*, 2011).

Michael Rosen *et al* studied 1,347 patients who underwent laparoscopic cholecystectomy at the Cleveland Clinic Foundation, USA from January 1996 to January 2000. 5.3% of the cases required conversion to open cholecystectomy and he concluded that morbidly obese patients with chronic cholecystitis, thickened gallbladder wall > 4mm and white cell count >9000 are more likely to require conversion. (Rosen M *et al.*, 2002).

Samer A. Kanaan *et al* reviewed records of 564 laparoscopic cholecystectomy patients in Northwestern Memorial Hospital, USA for a period of 2 years (1995-1996). The results showed that 161 of 564 patients had acute and 403 patients had chronic cholecystitis; 16 acute cholecystitis patients (10%) were converted from laparoscopic cholecystectomy to open cholecystectomy and 17 chronic cholecystitis patients (4%) were converted to open surgery. Patients having open conversion were

significantly older, had greater prevalence of cardiovascular disease, and were more likely to be males with a greater leukocyte count (Samer AK *et al.*, 2002).

Jeremy M. Lipman *et al* performed retrospective review of 1377 patients for benign gallbladder disease over a 71-month period (January 2000 through November 2005) who underwent laparoscopic cholecystectomy. There were 112 (8.1%) conversions to open cholecystectomy and multivariate analysis identified male gender, elevated white blood cell count, low serum albumin, ultrasound finding of pericholecystic fluid, diabetes mellitus, and elevated total bilirubin as independent predictors of conversion (Jeremy ML *et al.*, 2007).

Hun TS *et al* performed retrospective study in Hospital Tuanku Ja'afar Seremban, Malaysia where outcome of laparoscopic cholecystectomy in 200 patients from January 2013 to December 2014 was analysed. The rate of conversion to open cholecystectomy was 14% with male gender, diabetes mellitus and acute cholecystitis being the independent risk factors for conversion (Hun TS *et al.*, 2017).

Teoh MS *et al* analysed the conversion rate of laparoscopic to open cholecystectomy in Hospital Universiti Sains Malaysia for 75 patients from January 2003 until December 2004. The conversion rate was noted to be 16% with main reason being unclear anatomy intra operatively (Teoh MS *et al.*, 2005).

ii. **RATIONALE OF STUDY**

- ◆ To audit cases of laparoscopic cholecystectomy performed in Hospital USM for a period of 2 years
- ◆ To identify number of conversion of laparoscopic to open cholecystectomy
- ◆ To identify the risk factors associated with conversion of laparoscopic cholecystectomy to open surgery
- ◆ Compare data of laparoscopic cholecystectomy and conversion rate in Hospital Universiti Sains Malaysia to other institutions
- ◆ To lower threshold for conversion in high risk patient to decrease operative time and prevent complications
- ◆ For a better preoperative planning in high risk patients(e.g more experienced surgeon, better explanation to patient about high risk of conversion, complications associated and longer hospital stay)

B. STUDY PROTOCOL

- i. Document submitted to for ethical approval

INTRODUCTION

Nowadays the gold standard for treatment of patients with symptomatic gallbladder disease is laparoscopic cholecystectomy which has replaced open surgery (Rosen M *et al.*, 2002; Cuschieri A *et al.*, 1991; Hollington P *et al.*, 1999; Ibrahim S *et al.*, 2006). The advantages of laparoscopic surgery are decreased postoperative pain, earlier oral intake, shorter hospital stay, early resumption of normal activity and improved cosmesis (Wei-Jie Z *et al.*, 2008). However 2-15% of laparoscopic cholecystectomies still need to be converted to open surgery for various reasons (Rosen M *et al.*, 2002). Numerous patient and disease-related factors, such as male gender, obesity, old age (65), prior abdominal surgery, acute cholecystitis, choledocholithiasis, and anomalous anatomy have been reported as significant risk factors for conversion to the open procedure (Livingston EH *et al.*, 2004; Liu CL *et al.*, 1996; Tang B and Cuschieri A, 2006; Ibrahim S *et al.*, 2006; Sujit VS *et al.*, 2010). Therefore identification of the preoperative parameters that are risk factors for possible conversion would be useful for both patients and surgeons (Ibrahim S *et al.*, 2006).

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excessive expense (Rosen M *et al.*, 2002). The ability to accurately identify an individual patient's risk for conversion based on preoperative information can result in more meaningful and accurate preoperative counselling, improved operating room scheduling and efficiency, stratification of risk for technical difficulty, and appropriate assignment of resident assistance, may improve patient safety by minimising time to conversion, and helps to identify patients in whom a planned open cholecystectomy is indicated (Jeremy ML *et al.*, 2007).

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ii. **RATIONALE OF STUDY**

- ◆ To audit cases of laparoscopic cholecystectomy performed in Hospital USM for a period of 2 years
- ◆ To identify number of conversion of laparoscopic to open cholecystectomy
- ◆ To identify the risk factors associated with conversion of laparoscopic cholecystectomy to open surgery
- ◆ Compare data of laparoscopic cholecystectomy and conversion rate in Hospital Universiti Sains Malaysia to other institutions
- ◆ To lower threshold for conversion in high risk patient to decrease operative time and prevent complications
- ◆ For a better preoperative planning in high risk patients (e.g. more experienced surgeon, better explanation to patient about high risk of conversion, complications associated and longer hospital stay)

GENERAL OBJECTIVE

1. A retrospective study of laparoscopic cholecystectomies performed in Hospital University Sains Malaysia and comparing risk factors between laparoscopic cholecystectomy group and laparoscopic converted to open cholecystectomy group

SPECIFIC OBJECTIVES

1. To audit number and pattern of laparoscopic cholecystectomy in Hospital USM
2. To determine number / rate of conversion of elective laparoscopic cholecystectomy to open cholecystectomy
3. To identify demographics (age, gender, race) as a risk factor for conversion of laparoscopic cholecystectomy to open cholecystectomy
4. To identify association between risk factors and conversion of laparoscopic cholecystectomy to open cholecystectomy
 - A. preoperative laboratory results (ALP, ALT, WCC)
 - B. preoperative radiological findings (presence or absence of gallstones, gallbladder wall thickness)
 - C. postoperative histopathological results (acute v/s chronic cholecystitis)

RESEARCH HYPOTHESIS

- ◆ H0 : There is no association between risk factors (age, gender, race, ALT, ALP, WCC, presence of gallbladder stones, gallbladder wall thickness, histopathological diagnosis) and conversion of laparoscopic cholecystectomy to open cholecystectomy

- ◆ H1 : There is association between risk factors (Age, gender, race, ALT, ALP, WCC, gallbladder stones, gallbladder wall thickness, histopathological diagnosis) and conversion of laparoscopic cholecystectomy to open cholecystectomy

RESEARCH DESIGN

- ◆ Retrospective review of medical records in Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan from October 2013 to December 2015.

- ◆ Participants involve all the patients who electively underwent laparoscopic cholecystectomy in Hospital University Sains Malaysia and fulfil the inclusion/ exclusion criteria.

SAMPLE SIZE CALCULATION

◆ Using the single proportion formula

$$◆ \quad n = (z/\Delta)^2 p(1-p)$$

$$◆ \quad n = (1.96/0.05)^2 0.07(0.93) = 100$$

$$◆ \quad \text{Drop out } 20\% = 20$$

$$◆ \quad \text{Sample size} = 100 + 20 = 120$$

SAMPLING FRAME

◆ INCLUSION CRITERIA

1. Patients who underwent elective laparoscopic cholecystectomy in Hospital Universiti Sains Malaysia from October 2013 to December 2015
2. Patients above age of 18 years

◆ EXCLUSION CRITERIA

1. Patients less than 18 years
2. Cases with suspected or confirmed biliary tree malignancy
3. Cases with incomplete data from records
4. Emergency operations
5. Patients undergoing other surgery at the same setting as laparoscopic cholecystectomy
6. Patients who were already planned for open cholecystectomy in the first place

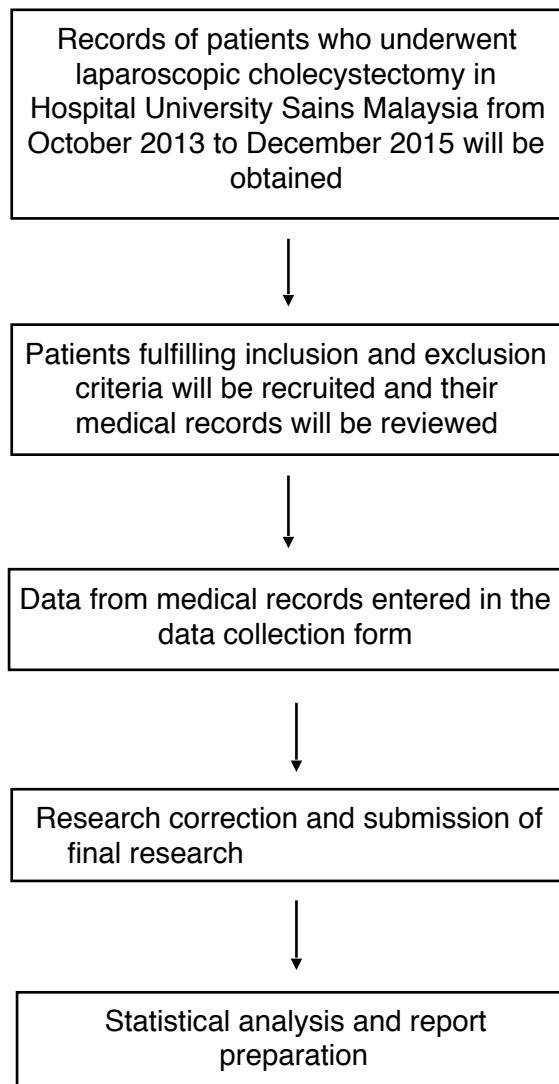
DATA COLLECTION AND ANALYSIS

- ◆ Data collection forms (Appendix 1) will be prepared and filled up from patient records
- ◆ Statistical analysis will be done using the SPSS software (univariate analysis using t-test and Chi-squared test; multivariate analysis for multiple logistic regression)
- ◆ p-value of <0.05 will be considered as statistically significant

ETHICAL ISSUES

1. There is no conflict of interest in this study.
2. The medical information of each subject will be kept confidential and will not be made publicly available unless disclosure by law is required. The data which will be obtained from this study might be published for knowledge purposes; provided that the discretion of the subjects is maintained.

FLOW OF STUDY



GANTT CHART

Year	2016							2017											
	J u n	J u l	A u g	S e p	O c t	N o v	D e c	J a n	F e b	M a r	A p r	M a y	J u n	J u l	A u g	S e p	O c t	N o v	D e c
Proposal presentation	█	█	█	█															
Ethics approval					█	█	█												
Discussion with supervisor	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█
Data collection									█	█	█	█							
Data analysis and report presentation											█	█	█	█	█	█			
Submission of draft and revision																█	█	█	
Submission of final research																		█	█

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DATA COLLECTION SHEET

Patient No:

DEMOGRAPHICS:

Age:.....

Gender: Male / Female

Race: Malay / Chinese / Indian / Others

OPERATIVE DETAILS

Date of admission:

Date of discharge:

Operation done:

Date of operation:

PRE OPERATIVE LABORATORY RESULTS:

White cell count:

Alkaline phosphatase:

Alanine transferase:

PRE OPERATIVE ULTRASOUND FINDINGS:

Presence of gallstone: Yes / No

Gall bladder wall thickness:

POST OPERATIVE HISTOPATHOLOGICAL REPORT:

.....

.....

ii. Ethical approval letter



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

29th March 2017

010-360 7355

Dr. Iqtidaar Oaris

Department of Surgery

School of Medical Sciences

Universiti Sains Malaysia

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www.jepem.kk.usm.my

JEPeM Code : USM/JEPeM/16120602

Protocol Title : Laparoscopic Cholecystectomy Conversion Rate and the Associated Risk Factors in Hospital USM.

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/16120602**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **29th March 2017** until **28th March 2018**.

Study Site: Hospital Universiti Sains Malaysia.

The following researchers also involve in this study:

1. Dr. Maya Mazwin Yahya
2. Assoc. Prof. Dr. Zaidi Zakaria

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. Data Collection Sheet

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. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2015: Continuing Review Application Form**. Subsequently this need to be done yearly as long as the research goes on.
2. 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) 2015: Study Protocol Amendment Submission Form**.
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2015: Study Protocol Amendment Submission Form**.
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2014: Adverse Events Report**.
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2015**.
6. Any event which may have ethical significance.

7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2014: Final Report Form.**

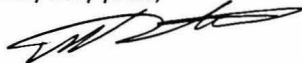
Please note that forms may be downloaded from the JEPeM-USM website: www.jepem.kk.usm.my

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

"ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,



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

Date of meeting : 2nd March 2017
 Venue : Meeting Room, Division of Research & Innovation,
 USM Kampus Kesihatan.
 Time : 9.00 a.m – 2.30 p.m
 Meeting No : 355

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 16150 Kubang Kerian,
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Members of Committee of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia who reviewed the protocol/documents are as follows:

Member (Title and Name)	Occupation (Designation)	Male/ Female (M/F)	Tick (✓) if present when above items, were reviewed
Chairperson : Professor Dr. Hans Amin Van Rostenberghe	Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Chairperson)
Secretary: Mr. Mohd Bazlan Hafidz Mukrim	Science Officer	M	✓
Members :			
1. Assoc. Prof. Dr. Azlan Husin	Lecturer, School of Medical Sciences	M	✓
2. Assoc. Prof. Dr. Haslina Taib	Lecturer, School of Dental Sciences	F	✓
3. Assoc. Prof. Dr. Mohtar Ibrahim	Lecturer, School of Medical Sciences	M	✓
4. Prof. Dr. Narazah Mohd Yusoff	Lecturer, Advanced Medical and Dental Institute (AMDI)	F	✓
5. Prof. Dr. Nik Hazlina Nik Hussain	Lecturer, School of Medical Sciences	F	✓
6. Mrs. Norleha Mohd Noor	Executive Secretary, School of Dental Sciences	F	✓
7. Associate Professor Oleksandr Krasilshchikov	Lecturer, School of Health Sciences	M	✓
8. Dr. Soon Lean Keng	Lecturer, School of Health Sciences	F	✓
9. Mrs. Zawiah Abu Bakar	Community Representative	F	✓
10. Prof. Dr. Zeehaida Mohamed	Lecturer, School of Medical Sciences	F	✓

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.


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