INFORMED CONSENT (ENGLISH)

Name of Principal Investigator	-	Dr. Min Nay Zar Wyke
Name of Organization	-	Department of Surgery Defence Services Medical Academy
Name of Sponsor	-	Nil
Title of Proposal	-	Comparative study of conventional versus two ports plus one puncture laparoscopic cholecystectomy

PART I. Information Sheet

(1) Introduction

I am Dr. Min Nay Zar Wyke, and I am going to carry out this research in laparoscopic cholecystectomy for symptomatic gall stones by means of conventional and two ports plus one puncture. I will explain you about the necessary information for this research. I also invite you to take part in this research. But, you have no need to decide for the participation in this research immediately. You can also consult with others and take advice from them. Concerning with the explanation for this research, you can ask me immediately about this if you do not understand it. You can also ask me later in any time about it.

(2) Purpose

The purpose of this study is to carry out a comparative study of conventional laparoscopic cholecystectomy and two ports plus one puncture laparoscopic cholecystectomy for symptomatic gall stones patients who admitted to No.(1) Military Hospital (700 bedded) Pyin Oo Lwin. By means of this research, we can study comparatively advantages and dis advantages of each treatment, and we can study which treatment is better than for patients. These research findings can help us how to choose the best way for the management of symptomatic gall stones in future.

(3) Type of Research Intervention

This research is comparative, prospective, hospital-based interventional, randomized controlled trial study by the procedure of conventional laparoscopic

cholecystectomy and two ports plus one puncture laparoscopic cholecystectomy for symptomatic gall stones patients.

(4) Participant selection

According to inclusion and exclusion criteria, all patients with symptomatic gall stones will be selected from the surgical wards of No. (1) Military Hospital (700 bedded) Pyin Oo Lwin.

(5) Voluntary participation

Your participation in this research is entirely voluntary. You have no disturbances for your personal freedom due to this research. If you choose not to participate, nothing will change in your treatment plan. You can also quite from the research any time if you do not want to participate in the research anymore, and it will change nothing in your treatment plan.

(6) Procedure

Symptomatic gall stones patients, who meet inclusion criteria will be recruited within two years period at No. (1) Military Hospital (700 bedded), Pyin Oo Lwin. They will be explained about the study procedure that they will be undergone either conventional laparoscopic cholecystectomy and two ports plus one puncture laparoscopic cholecystectomy.

In conventional laparoscopic cholecystectomy, the procedure will be done with four ports which will be placed 10 mm port in the subumbilical region, another 10 mm port in the subxiphoid epigastric region, 5 mm port in the right subcostal midclavicular line and another 5 mm port in the right subcostal anterior axillary line location.

In two ports plus one puncture laparoscopic cholecystectomy, the procedure will be done with two ports, which will be placed 10 mm port in the subumbilical region, 5 mm port in the subxiphoid epigastric region, and with 2.3 mm alligator grasper which will be punctured below the right costal margin.

All patients will be fully informed about the procedures of two methods and their complications in easily understandable terms. All patients, who give written informed consent, will be included in the study.

The selected patients will be randomly posted in groups of conventional laparoscopic cholecystectomy and two ports plus one puncture laparoscopic cholecystectomy. All the records from the study will be kept confidential. The reports

on analysis of the data from the study may be published in the future; however, privacy of the participant will be strictly maintained. You are free to withdraw from the study anytime without affecting the medical care of you.

(7) Duration

This research will take at least 2 weeks for each participant. The mean operation time for conventional laparoscopic cholecystectomy will be about 40 minutes and for two ports plus one puncture laparoscopic cholecystectomy about 50 minutes.

(8) Risks

In this study, conventional laparoscopic cholecystectomy and two ports plus one puncture laparoscopic cholecystectomy will be compared.

Conventional laparoscopic cholecystectomy is still gold standard procedure up to now. Although accepted procedure, it still has chance of complications like wound infection, pain, bleeding and injury to nearby structures (bile duct, bowel, liver). Among these injuries, bile duct injury is common and the percentage may be 1% to 2%. Conversion to open procedure from conventional laparoscopic cholecystectomy will be performed where there is difficulty to identify the important anatomy due to dense adhesions and inflammation, and complications such as bile duct injury, uncontrolled bleeding occurred. The rate of open conversion from conventional laparoscopic cholecystectomy will be less than 1%.

Two ports plus one puncture laparoscopic cholecystectomy is also acceptable procedure but it can carry longer operation. It also has chance of complications like wound infection, pain, bleeding and injury to nearby structures (bile duct, bowel, liver) as conventional laparoscopic cholecystectomy. The percentage of bile duct injury may be 1% to 3%. If there is difficulty to identify the important anatomy due to dense adhesions and inflammation, and complications such as bile duct injury, uncontrolled bleeding occurred, treatment can be converted to conventional procedure (about 5.45%) or open procedure (about 0.18%).

Complications will be treated accordingly. Pain will be treated according to pain treatment guideline. All the information and the results from this study will be confidential. The study will not interfere the treatment planned according to hospital guideline.

(9) Discomforts

By participating in this research it is possible that you may experience some discomfort due to laparoscopic cholecystectomy.

(10) Benefits

By participating in this research, if you are in the group of conventional laparoscopic cholecystectomy, your disease will be removed immediately after surgery and its operation time is relatively less than contralateral technique.

On the other hand, if you are in the group of two ports plus one puncture laparoscopic cholecystectomy, you will not have inferior treatment outcomes. This technique can maintain the principle as the conventional technique and the advantages such as reduce number of port, reduce size of port, less painful and higher cosmesis can be obtained. No matter what, your participation is likely to help us in obtaining information for future treatment in symptomatic gall stones.

(11) Incentives

You will not get any incentives in cash by involving in this study.

(12) Confidentiality

All the records from the study will be kept confidential. It will be shared only between the responsible persons. The reports on analysis of the data from the study may be published in the future; however, privacy of the participants will be strictly maintained.

(13) Sharing the Results

The knowledge that we get from this research will be shared for future treatment of symptomatic gall stones. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

(14) Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop

participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.

(15) Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at the hospital in accordance with your health problem.

(16) Who to Contact

If you have any questions you may ask me now or later; even after the research has started. If you wish to ask questions later, you may contact any of the followings:

Dr. Min Nay Zar Wyke
Department of Surgery,
Defence Services Medical Academy, Mingalardon
minnayzarwyke3681@gmail.com
Ph.095501867

If there are any complaints about this study or principal investigator, the participant can also contact to ethical review committee DSMA.

Prof. Lt.Col. Daw Mo Mo Than
Professor and Head
Department of Biochemistry
Defence Service Medical Academy, Mingalardon
momomoekyaw@gmail.com
Ph.095143107

Part II. Certificate of consent

(A) Purpose of the study

The purpose of this study is to study the comparison between conventional laparoscopic cholecystectomy and two ports plus one puncture laparoscopic cholecystectomy. These research findings can help in our national health project management. If you agree to participate in this study, you are requested to follow our instructions guideline according to our research protocol.

The information you provide is very confidential and it will not be disclosed to anyone. It will be removed from the questionnaires and use of your answer without identifying.

(B) Declaration of the volunteer

I have been invited to participate in comparative study of conventional laparoscopic cholecystectomy and two ports plus one puncture laparoscopic cholecystectomy. I am aware that there may be no incentive to me personally. I have been provided with the name of the researcher who can be contacted using the phone number and address. I have read the foregoing information or it has been read to me. I have had the opportunity to ask questions about it, and any questions that I have asked have been answered to my satisfaction. I consent voluntarily and also there is no threat and undue influence of the investigator or any other persons to participate as a subject in this study. I understand that I have the right to withdraw from the study at any time without affecting further medical care to me in any way.

Name of Participant _____

Signature of Participant _____

Date (Day/month/year) _____

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of Witness _____

Signature of Witness _____

Date (Day/month/year) _____

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of Researcher _____

Signature of Researcher _____

Date (Day/month/year) _____

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness_____

Signature of witness _____

Date (Day/month/year) _____

Left Thumb print of participant

Name of Researcher_____

Signature of Researcher _____

Date (Day/month/year) _____

Note: A copy of this informed consent form is handed to the participant.