PARTICIPANT INFORMATION SHEET AND CONSENT FORM

STUDY INFORMATION

Protocol Title:

A randomised controlled trial comparing conventional haemorrhoidectomy and laser haemorrhoidectomy in the treatment of haemorrhoids: COHLAH trial

Principal Investigator:

Dr Foo Fung Joon
Head of Service, Colorectal Surgery

Address:
Division of Colorectal Surgery
Department of General Surgery
Sengkang General Hospital
110 Sengkang East Way
Singapore 544886

email: foo.fung.joon@singhealth.com.sg

Tel no.: (+65) 6930 5354
Urgent after office hours contact: (+65) 6930 6000

PURPOSE OF THE RESEARCH STUDY

You are being invited to participate in a research study. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

The purpose of this study is to directly compare the conventional open haemorrhoidectomy technique (COH) ('cutting out the haemorrhoids surgically') to the laser haemorrhoidectomy procedure (LAH) (using laser emission probe to burn off the haemorrhoids) in a local Asian population. We hope to learn that the benefits of LAH include significantly less pain, bleeding and better initial Quality of Life (QoL) scores.

You were selected as a possible participant in this study because you have haemorrhoids that are big enough to come out through the anus and would benefit from a surgical procedure.

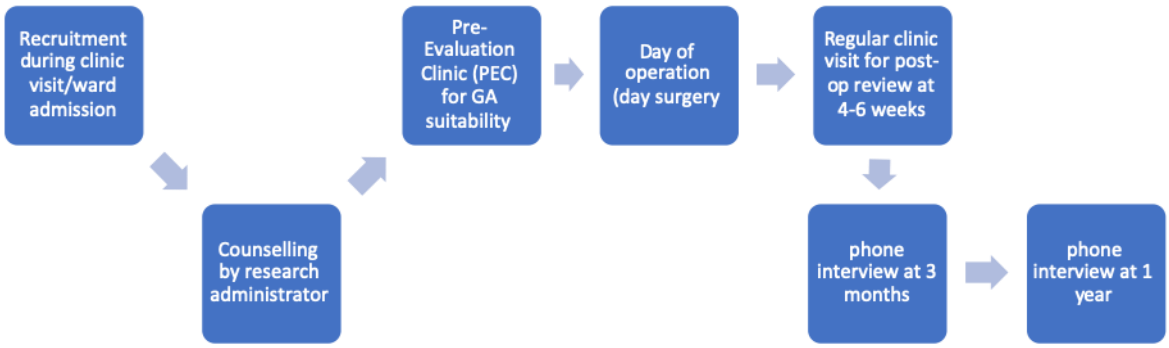
This study will recruit 128 participants from Sengkang General Hospital.

STUDY PROCEDURES AND VISIT SCHEDULE

If you agree to take part in this study, you will be randomised to receive either the conventional open technique (COH) or the laser haemorrhoidectomy procedure (LAH) as treatment for your haemorrhoids. Randomisation means assigning you to one of 2 groups by chance, like tossing a coin or rolling dice.

If you agree to take part in this study, you will be asked to complete a questionnaire after you have given consent, during the first 10 days after your operation and receive 2 additional phone calls to check on your progress 3 months and 1 year after your operation. Your participation in the study will last 1 year after your operation. You will undergo the operation once and be followed up for 1 year after your operation. You will need to visit the doctor's office 3 times in the course of the study, which is in keeping with the expected number of visits after the operation if you were not part of this trial.

Schedule of visits and procedures:



Timeline of participation. Those in the 1st row are regarded as within normal clinical practice. Those in the 2nd row are regarded as outside of normal clinical practice.

In addition, your data collected during the study may be kept for future research beyond the completion of the study. For this purpose, consent for future research will be sought from you.

YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to participate in this study, you should:

- Follow the advice given to you by the study team.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Inform the Principal Investigator as soon as possible about any side effects that you may have encountered.
- Be prepared to visit the hospital 3 times and undergo all the procedures that are outlined above.

WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY

The study is being conducted because laser haemorrhoidectomy procedure (LAH) is not yet proven to be a standard treatment in participants with symptomatic haemorrhoids, even if preliminary data from Europe, Middle East and parts of Asia are promising. We hope that your participation will help us to determine whether LAH is equal or superior to existing conventional open haemorrhoidectomy (COH).

Use of blinding (one or more parties unaware of the treatment assignment), and randomization (study technique selection by chance) are only done for research studies. You would be informed of the allocation only at the clinic review at 4-6 weeks.

As LAH may not be part of standard medical care, in this study, this procedure is being performed for the purposes of the research.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

Risk of Laser haemorrhoidectomy procedure (LAH):

- Bleeding (<1 in 100)
- Clotting of the haemorrhoids leading to pain and swelling (<1 in 100)
- Anal muscle injury which may lead to anal narrowing or loosening that results in inability to control bowel movements (<1 in 1000)
- Infection (<1 in 100)
- Bowel injury which may necessitate emergency surgery and/or bringing up the intestine to the skin as a temporary pouch (<1 in 1000)
- Intestinal obstruction which may necessitate bringing up the intestine to the skin as a temporary pouch (<1 in 1000)

POTENTIAL BENEFITS

If you participate in this study you may reasonably expect to benefit from the study intervention in the following way:

Patients will be closely monitored post procedure for their pain and symptoms and will receive a phone calls outside the regular follow up period, up to a year post-procedure, to follow up on their haemorrhoid-related symptoms.

They will also potentially may receive a procedure that could potentially cause less pain and have a lower risk of post-operative bleeding with no additional cost compared to the conventional technique.

IMPORTANT INFORMATION FOR WOMEN PARTICIPANT

The effect of the use of laser on a baby's development is not known. Therefore, pregnant and breast-feeding women may not take part in this study. Women who have a chance of becoming pregnant must have a negative pregnancy test at study entry and use birth control during the study. If you become pregnant prior to your operation, you must call your doctor or the Principal Investigator immediately.

ALTERNATIVES

If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution this would be the conventional open haemorrhoidectomy.

This alternative procedure has the following potential benefits:

- surgical removal of haemorrhoids
- accepted to have low risk of recurrence

and the following potential risks:

Risk of Conventional open haemorrhoidectomy:

- Bleeding (1 to 5 in 100)
- Anal muscle injury which may lead to anal narrowing or loosening that results in inability to control bowel movements (<1 in 1000)
- Infection (<1 in 100)
- Recurrence of haemorrhoids (1 in 10)

COSTS OF PARTICIPATION

If you take part in this study, both groups will pay the same bill as per conventional open haemorrhoidectomy (regardless the treatment type they are assigned to). Additional costs from the laser haemorrhoidectomy will be covered by the study team.

If you take part in this study, you will have to pay for the following:
- The usual cost of the conventional open haemorrhoidectomy
- medications to be consumed/applied post-operatively

You will also receive 2 additional phone calls at 3-months and 1-year after your operation to complete a short verbal questionnaire pertaining to your QoL.

INCIDENTAL FINDINGS

During the course of the study, there is a possibility that we might unintentionally come to know of new information about your health condition from endoscopic assessment, pre-operative blood tests, X-rays and anaesthetic assessment that are conducted as part of the study. These are called “incidental findings”.

“Incidental findings” are findings that have potential health or reproductive importance to participant like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. These findings may cause you to feel anxious and may affect your current or future life and/or health insurance coverage. You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.

If you agree to be re-identified and notified, your study doctor will explain the incidental finding to you and discuss and advise you on the next steps to follow. You may wish to do more tests and seek advice to confirm this incidental finding. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

PARTICIPANT’S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

By signing and participating in the study, you do not waive any of your legal rights to revoke

your consent and withdraw from the study at any time.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study, or the study intervention is stopped for any reason,

- You will be notified though phone call from the study administrators prior to your surgery and by the study team on the operation day itself.
- We would still go ahead with the treatment for your haemorrhoids but with the conventional open haemorrhoidectomy technique.
- You are also to return all study-related documents at the earliest possible time.

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

Your doctor, the Principal Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons:

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful.
- Pregnancy between the time of recruitment and time of surgery.
- You need treatment not allowed in the study.
- The study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the trial substance or research procedure given under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment will not be provided by the Sengkang General Hospital.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study will involve the collection of Personal Data. Personal Data collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator(s) will have access to the confidential information being collected.

However, Regulatory Agencies, Institutional Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by Sengkang General Hospital, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties.

“Personal Data” means data about you which makes you identifiable (i) from such data or (ii)

from that data and other information which an organisation has or likely to have access. Examples of personal data include medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this “Personal Data”, will be subject to review by the relevant institutional review board.

Data collected and entered into the Case Report Form(s) or Data Collection Form(s) are the property of Sengkang General Hospital. In the event of any publication regarding this study, your identity will remain confidential.

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact the Principal Investigator:

Dr Foo Fung Joon
Head of Service, Colorectal Surgery

Address:
Division of Colorectal Surgery
Department of General Surgery
Sengkang General Hospital
110 Sengkang East Way
Singapore 544886

email: foo.fung.joon@singhealth.com.sg

Tel no.: (+65) 6930 5354
Urgent after office hours contact: (+65) 6930 6000

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 6323 7515 during office hours (8:30 am to 5:30pm).

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM

Details of Research Study

Protocol Title:

A randomised controlled trial comparing conventional haemorrhoidectomy and laser haemorrhoidectomy in the treatment of haemorrhoids: COHLAH trial

Principal Investigator:

Dr Foo Fung Joon

Head of Service

Division of Colorectal Surgery

Department of General Surgery

Sengkang General Hospital

110 Sengkang East Way

Singapore 544886

email: foo.fung.joon@singhealth.com.sg
Tel no.: (+65) 6930 5354
Urgent after office hours contact: (+65) 6930 6000

I agree to participate in the research study as described and, on the terms, set out in the Participant Information Sheet.

I have fully discussed and understood the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Consent to be Re-identified and Notified in the case of an Incidental Finding
As explained earlier, there may be potential incidental findings arising from this research.
Please indicate whether you will allow re-identification and be notified about the incidental finding:

☐ Yes, I agree to be re-identified and notified in the case of an incidental finding from this research. I can be reached by:

Phone/ Email:

In the event that I cannot be reached, please contact the following person nominated by me:
Name:
Phone/ Email:

☐ No, I do not agree to be re-identified and notified in the case of an incidental finding from this research. *(You may want to note that in exceptional situations such as discovery of life-threatening incidental findings with available treatment options, we may contact you to confirm your decision whether to learn more about the incidental findings.)*

Consent for the Use of Data for Future Research

Please indicate your options by indicating a tick (√) on the checkboxes:	**Yes**	**No**
Do you consent for your data to be used for future research?	☐	☐

_____	_____	_____
Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for the above participant to participate in the proposed research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant's parent/ legal guardian/ legal representative	Signature/ Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____by _____.

Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____

Name of witness | Date of signing

_____

Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant or legal representative thumbprint). After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained and clearly understands the nature, risks and benefits of his/ her/ his ward's/ her ward's participation in the study.

_____ _____ _____

Name of Investigator/ Person obtaining consent | Signature | Date