Please let the study team know if you need an interpreter.

PARTICIPANT INFORMATION SHEET

Butterfly Feasibility Study

Formal Study title:	**Surgical Treatment of stage I – II endometriosis: The Butterfly Feasibility (open pilot) study**
Protocol number:	1.0
Sponsor:	N/A
Lead Study Doctor:	Dr Jessica Dunning
Study Site:	Te Toka Tumai Auckland Hospital and Greenlane Surgical Unit
Contact phone number:	02885170053
Ethics committee ref.:	2025 FULL 24069

Taking part in this research is your choice.

You do not have to take part. If you choose not to take part or withdraw from the study, your normal care will not be affected.

- You will be given time to decide whether you want to take part in this study.

- The study team will discuss the study with you and answer any questions you have before you decide.
- You may talk to family, whānau, friends, or healthcare providers before you decide.
- If you have private medical insurance, you may wish to check whether this study will affect your cover.
- If you decide to take part, you will be asked to sign the Consent Form. You will also be given a copy of this information sheet and the signed consent.
- If you change your mind about taking part, you can withdraw from the study at any time by telling the study team.
- There may be no direct benefit to you from taking part in this study, and there may be risks of injury or illness.
- There will be a separate surgical consent form.

Introduction

You are invited to take part in a research study exploring a surgical treatment for endometriosis. Endometriosis is a long-term condition where tissue similar to the lining of the uterus grows outside of it, often causing pain and other symptoms. This tissue commonly appears on pelvic surfaces and can be difficult to identify during surgery.

Endometriosis is often described in stages based on how much endometriosis is seen at surgery. The stage does not necessarily reflect how severe a person's symptoms are.

Stage I–II endometriosis is considered mild. It usually involves small patches of endometriosis on the thin lining that covers the organs inside the pelvis (called the peritoneum). These patches are most often found near organs such as the uterus, ovaries, and fallopian tubes.

Stage III–IV endometriosis is more severe. It can involve larger areas of endometriosis, deeper growths into nearby tissues, cysts on the ovaries, and scar tissue that can cause organs in the pelvis to stick together.

This study includes people with mild (stage I–II) endometriosis only. We are not studying Stage III-IV endometriosis as the surgical management is more extensive for that group of patients.

The study is testing whether a different surgical technique, called *posterior peritonectomy*, can improve pain relief and quality of life for patients with early stage endometriosis. This procedure involves removing more of the peritoneum (the thin tissue layer lining the pelvic area behind the uterus), even if it does not show signs of endometriosis. This is because the peritoneum may have endometriosis, which is too small to see with the naked eye. This extra tissue removed is about the size of your palm. In contrast, the standard approach only removes areas of the peritoneum where

endometriosis is clearly seen. Peritoneum starts to regrow without endometriosis in 24 - 48 hours and is fully regrown over the next seven days.

We think that removing the extra margin of peritoneum may remove more microscopic endometriosis and therefore improve pain outcomes following surgery.

Posterior peritonectomy is commonly performed for more advanced endometriosis, so is not a new surgical procedure, just one that is not always performed for earlier stage endometriosis. It is not available by request at our hospital outside of this randomised trial.

What is the aim of this study?

This is a feasibility study to see if it is possible to recruit patients for a larger surgical trial and to provide baseline scores for the planned outcome measurement tools.

If the larger study goes ahead then the results from the feasibility study will be included in the larger trial.

It will also compare two established surgical techniques in people with stage I-II endometriosis and pelvic pain to see:

- How effective these two surgical procedures are at treating pain and improving quality of life
- What study participants think about the procedures involved in the study
- Whether participants can guess what treatment arm they were in

What type of study is this?

This is a single-site, participant-blinded, randomised controlled trial (RCT).

Randomised	This means you will be assigned to receive one of two surgical procedures randomly (by chance). The randomisation will be performed intraoperatively (during surgery) by the anesthesia or nursing team, once it is confirmed you have stage I-II endometriosis. You have a 1 in 2 chance of getting standard excisional treatment – which means your endometriosis will be excised from where it is seen. You have a 1 in 2 chance of getting a full posterior peritonectomy – which means your endometriosis will be excised with a wider margin of normal appearing tissue. You will not be able to choose which group you are in.
Blinded	This means that you and the study team (other than your surgeon) will not know which procedure you received. Blinding will be maintained until 12 months after randomisation, at which point your treatment arm will be revealed if you wish. If you change your mind, you can be unblinded earlier. You just need to let the research nurse know this is your wish. Blinding is important because how people report their symptoms might change if they know what procedure they had.

How is the study designed?

Auckland & Greenlane Hospitals	This study is being run in New Zealand only at Te Whatu Ora - Te Toka Tumai Auckland Hospital and Greenlane Surgical Unit.
20 Participants	About 20 people will take part in this study and all will be in New Zealand.
12 months in Study	You will be in this study for about 12 months.
4 sets of online questionnaires	You will be asked to fill in questionnaires at baseline then 3, 6 and 12 months post op. These can be done online, over the phone or face to face. You will be offered one extra study visit at 12 months to see how you found the study and complete any outstanding questionnaires.

How will I take part?

There are two different surgical procedures being compared:

- Standard excisional treatment: All endometriosis that the surgeon can see is removed, leaving behind any normal-appearing peritoneum.
- Posterior peritonectomy: This involves removing all endometriosis that the surgeon can see with a wider margin of normal appearing peritoneum in the area behind the uterus, which may contain microscopic endometriosis.

You will receive standard postoperative care. In addition, you will be asked to complete a questionnaire prior to surgery, and 3, 6, and 12 months post-op. These will be emailed to you to fill in online. If you are unable to complete these online our research nurse can call you to do the questionnaires over the phone or organise to meet you and do them face-to-face.

Who can take part in the study?

To take part in this study you must:	
✓	Be a person with a uterus between 18 and 50 years old
✓	Be undergoing a laparoscopy for pelvic pain with suspected stage I-II endometriosis
✓	Have no previous surgical treatment for endometriosis (a diagnostic laparoscopy and biopsy are acceptable)
✓	Agree to take part in the study

You cannot take part in this study if you:	
✗	Have had a previous hysterectomy or bilateral oophorectomy
✗	Are pregnant
✗	Are presumed to have stage III-IV endometriosis before surgery (usually this is based on ultrasound findings)

There are other criteria you must meet to be eligible for the study. The study team will discuss all of them with you to make sure you are able to take part.

What will taking part in the study involve?

Screening (1-7 days)

If you decide to take part, you will be asked to sign the consent section at the end of this form.

The study team will then check whether you meet all the criteria to take part. This is called Screening.

- Screening must be done prior to surgery.
- It may be done on a single day or over several days.
- You will be told if you can take part once all your results have been checked.

Intervention and Follow-up (12 months)

You will undergo laparoscopic (keyhole) surgery to excise endometriosis. Your surgeon will perform either standard excisional treatment, where just the endometriosis that the surgeon can see is excised; or the endometriosis will be excised with a wider margin of normal appearing tissue (posterior peritonectomy). Any endometriosis in other areas of the abdomen (belly) will be treated as discussed with your surgeon. In both arms, all endometriosis the surgeon can see will be excised.

Whether you receive the standard surgical excision or a surgical excision with a wider margin will be determine at random while you are under anaesthesia.

After your surgery, you will be told whether endometriosis was found, what stage it was, and whether all of the endometriosis that the surgeon could see was removed. You will also be informed about any complications or other issues that occurred during the surgery. This is the same information that patients are routinely given after surgery, whether or not they take part in this study.

You will not be told which arm of the study you were in, if you wish to know, you can be told at your 12-month follow-up.

If you receive a posterior peritonectomy, the surgery is expected to take about 10 minutes longer.

The excised areas heal with new peritoneum in about seven days. We expect your recovery to be similar no matter which treatment you receive.

If the surgeon does not see any endometriosis, we will take biopsies of the lining of the pelvis and then ask you to do the same follow up questionnaires at 3, 6 and 12 months.

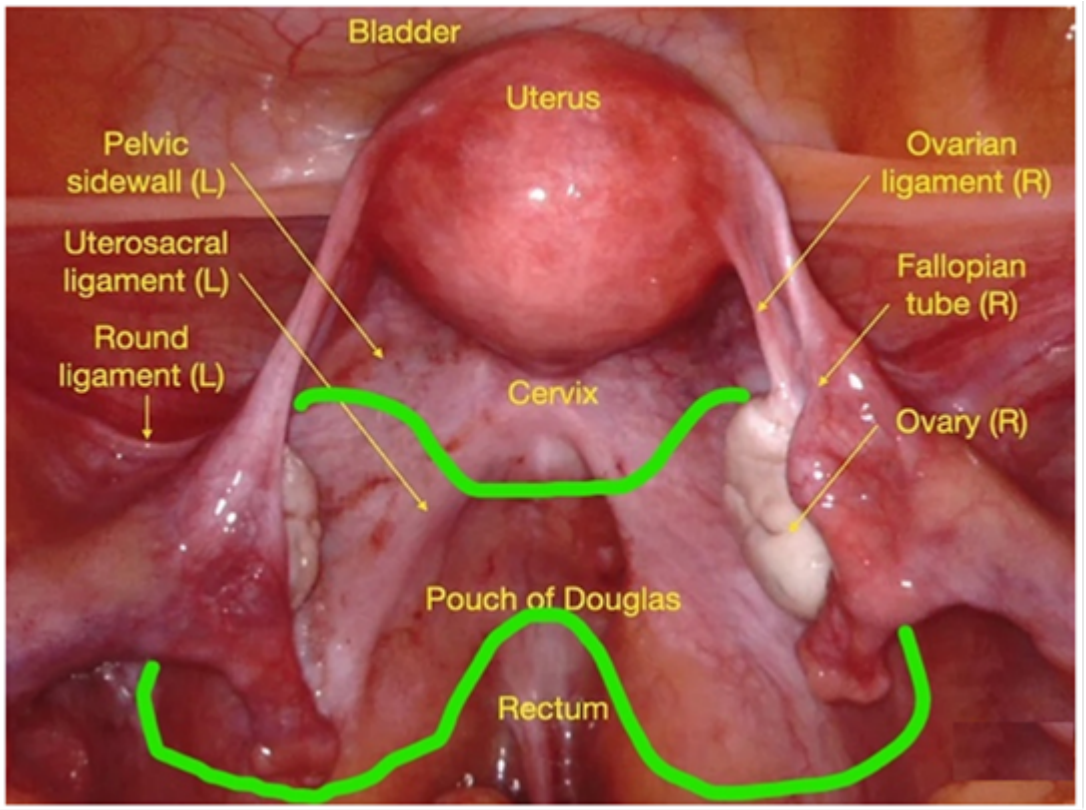

Figure 1. The surface of the pelvis outlined in green above will be excised (posterior peritonectomy). Standard excisional treatment involves excision of smaller areas within this region. Endometriosis outside the outlined region will be removed using standard methods. The area in green is about the size of your palm.

You will be asked to complete online questionnaires before your surgery and at 3, 6, and 12 months after. These will be emailed to you. If you are unable to complete these online our research nurse can call you to do the questionnaires over the phone or meet you and do them face-to-face.

After surgery you will also have a face-to-face follow up at 3 months – this is standard after any endometriosis surgery in our clinic. You will also be offered an extra appointment at 12 months to see how you found the study.

At each visit, you will have some of the assessments listed on the next page.

The table on the next page gives a summary of what will happen at each visit.

You may be asked to come to extra visits if the study team thinks this is needed for safety or other reasons.

If your study doctor identifies any significant abnormal results during the study, they will tell your GP.

Early withdrawal

If you decide you want to withdraw from the study, please let us know. At the point you withdraw you will be asked if you consent for the use of any data collected prior to the point of your withdrawal. You may at this time withdraw your consent for any of your data to be used.

Study Assessments

Informed consent	You will read and sign an informed consent form before you take part.
Eligibility check	We will check that you qualify for the study.
History and demographics	We will review your medical and surgical history, pregnancy history and plans, medications, and lifestyle choices relevant to the study and record your age, gender, and ethnicity.
Height and weight	We will check your height and weight.
Questionnaires	You will fill in some questionnaires about pain, mental wellbeing, medication use, activity, and quality of life. These questions will be answered on an electronic device. You will learn how to use it during screening. If you do not have access to a computer, we can arrange for the research nurse to meet with you and help you fill in the online forms.
Physical examination	A doctor will examine you during your Gynaecology clinic appointment. These examinations are part of a routine Gynaecology clinic appointment and are the same if you take part in the study or not. During your post-surgical 3-month review your belly may be examined to check for healing and pain – this is routine postoperative care and is not any different if you agree to this study.
Pregnancy tests	If you can get pregnant, you will have a urine pregnancy test before surgery. Surgery will be postponed if pregnancy is confirmed; this may mean you cannot take part in the study.
Health and Medication Check	We will ask you about any changes in your health and any changes to your medications. This includes prescription and over-the-counter medications, herbal or homeopathic remedies, and nutritional supplements.
Phone call	The study team will contact you to remind you to complete questionnaires if necessary.

Study contact points

Study Visit	Initial Gynaecology clinic appointment	Consent appointment – phone, online or face to face	Surgery	3 month post-op questionnaire - online	6 month post-op questionnaire - online	12 month follow-up visit – online or face to face
Time needed	30 min	30 min	1 day	15 min	15 min	30 min
Informed consent		x				
Eligibility check	x					
History & demographics	x					x
Vital signs	x					
Height and weight	x					
Physical exam	x					
Pregnancy test			x			
Health & Medication Check	x					x
Questionnaire(s)		x		x	x	x

What are my responsibilities during the study?

You should:	
✓	Complete online questionnaires before your surgery and at 3, 6, and 12 months after
✓	Tell a member of the study team if you have questions, comments, or decide you no longer wish to take part in the study
✓	Let the study team know if you change your phone number or address so we can contact you

You should not:	
✗	Agree to take part if you do not want a posterior peritonectomy (prefer to only remove tissue with endometriosis)
✗	Agree to take part if you need to know which treatment arm you received within 12 months of surgery
✗	Attempt to find out which treatment arm you received

What are the possible benefits of the study?

You may not get any direct benefit from being in the study. The posterior peritonectomy surgery may or may not improve your pain more than the standard surgical approach. However, your participation will help future patients by improving knowledge about surgical options for early-stage endometriosis.

What are the possible risks of the study?

Risks from any laparoscopic surgery can include bleeding, infection, injury to internal organs, and complications from anesthesia. The posterior peritonectomy procedure may have a small additional surgical risk due to a larger area of peritoneum being removed. The additional risks could include a small increase in blood loss, increased postoperative pain, or a higher chance of developing scar tissue (adhesions). These risks will be minimised by having only experienced surgeons perform the procedures and by using Adept anti-adhesion fluid to reduce the risk of adhesions.

You should contact us if you experience any changes in your health.
Your GP or other healthcare professionals may be contacted if we have concerns about your health, including your mental health.

The questionnaires you are asked to fill in have questions about your mental health. Although the questionnaires you will fill in are not designed to detect serious mental health risk, we acknowledge they may bring up thoughts or feelings of concern for you.

If significant mental health and wellbeing concerns are raised in the answers you give in the questionnaires, we will contact you to offer support. We may also need to inform your emergency contact or GP and we will refer you to the Urgent Response Team if required. If we can't contact you we will be required to inform your GP. Contact details for the Urgent Response Team will be provided on all questionnaires.

We will also offer you a referral through to the women's health psychology team and to the multi-disciplinary pain service if required.

Risks of laparoscopic surgery for endometriosis

Below is a list of potential complications and their frequency that can occur at the time of keyhole endometriosis surgery. These are standard surgical risks, and almost all of them are the same despite which treatment arm you are in. The risks that we think may be increased by a full peritonectomy are starred below (*). We will keep a record of all complications in the study.

Very common (seen in at least 10 in 100 people)
• Pain* • Nausea • Vomiting • Recurrence of pain/endometriosis

Common (seen in 1 - 10 in 100 people)
• Bleeding and bruising at the incisions on your belly • Infection in your wound • Difficulty passing wee • Constipation • Internal scarring (adhesions)*
Uncommon (seen in less than 1 in 100 people)
• Significant bleeding • Conversion to laparotomy (large abdominal cut) • Injury to the bowel, bladder, ureters, uterine tubes, ovaries, blood vessels, nerves • Blood clots in the veins requiring treatment • Hernia • Readmission to hospital • Return to the operating theatre to treat a complication

Unknown risks

Both surgical treatments are widely practiced, so it is unlikely there are any unknown risks.

New Information

If new information becomes available about alternative treatments for endometriosis, the study doctor will discuss it with you.

Reproductive risks and contraception

If you are pregnant, you will not be able to take part. Undergoing surgery may result in risks to a fetus or baby.

Will any costs be reimbursed?

There are no costs associated with taking part in this study, nor will you be paid.

You will receive a koha (a gift) after completing the surveys at 3, 6, and 12 months.

What if something goes wrong?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to

lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

What will happen to my samples?

- Excised peritoneum will be removed at the time of your surgery as part of standard surgical care.
- Samples sent to the local laboratory will be identified with your name and date of birth.
- Your samples will be kept for up to 1 year. They will then be destroyed using standard practices.
- If you wish to have your tissue returned to you after it has gone to the laboratory for assessment, we can organise this for you through the hospital.

You may hold beliefs about a sacred and shared value of any tissue samples removed. The cultural issues associated with storing your tissue should be discussed with your whānau as appropriate. We encourage you to discuss with your whānau to ensure you are comfortable with this

What will happen to my information?

We will collect information ('data') about you and your study participation. If needed, information from your hospital records may also be collected. We only collect information needed for the study, to contact you or identify your medical records. You cannot take part in the study if you do not want us to collect any of this information.

Identifiable information – *this information traces directly to you.*	
Examples?	Information carrying your name, birthdate, contact details, NHI number, and ethnicity,
How is it stored?	• Electronic: on secure University of Auckland servers
Who has access?	• Local study staff and health services that do your study assessments • Your GP / usual doctor [if needed] • Study monitors, to make sure data is collected properly • Study auditors (see below)
How long is it kept?	For at least 10 years

Coded information – *this information is labelled only with your unique study ID*

Examples?	Your gynaecologic history, endometriosis stage, your surgical note and any complications that occur, your surgical photos and video, any further treatment in the next 12 months and your questionnaire responses .
How is it stored?	• On a secure electronic server that complies with New Zealand data security guidelines.
Who has access?	• The research team within the University of Auckland and Te Whatu Ora.
How long is it kept?	For at least 10 years

Anonymous information – *this information cannot be linked to you in anyway*	
What is this?	Anonymised data will be irreversibly stripped of any identifying information
What does this mean	Anonymised data may be sent overseas for the purposes of contributing to pooled research outcomes (individual patient meta-analysis). There is unlikely to be New Zealand representation on overseas governance committees. Whilst the data can not be linked to you in any way we understand that this may raise cultural concerns for some participants.

Extra information about my data

Dr Jessica Dunning may need to share your identifiable information in the rare event of a serious threat to public health or safety, or to the life or health of you or another person, OR if the information is required in certain legal situations.

Audits: The study may be audited. Audits make sure studies are being carried out properly. Auditors need access to your identifiable study data and relevant health records to do this. The Sponsor, NZ or overseas regulatory agencies, or the approving Ethics Committee may do audits.

Data Access: You have the right to request access to information about you held by the research team, including the results of tests and procedures. You also have the right to request that any information you disagree with be corrected.

Study Withdrawal: You can ask the study team to stop collecting information about you at any time. This will end your participation in the study. Information collected up until this point will continue to be used, to protect the quality of the study.

Data Storage: After the study, your identifiable data will be stored for at least 10 years in a secure storage facility. Your coded data will be stored indefinitely on secure electronic servers. All storage will comply with local and/or international data security guidelines.

Data Risks

Although efforts will be made to protect your privacy, absolute confidentiality cannot be guaranteed. There is a risk that people may access or use your information in ways that you may not be acceptable to you.

Overseas laws will govern data sent overseas. These may not give as much protection as New Zealand laws.

Māori Data

We recognise Māori data is a taonga. Māori data sovereignty permits Māori organisations to access coded Māori data, to support Māori development aspirations. There is an understanding that Māori data are tapu and therefore to be respected and handled appropriately.

Could the study end earlier than planned for me?

If you wish to withdraw from the study, please let us know. We may ask if you could complete some end-of-study assessments if you withdraw early.

We may withdraw you from the study if we believe it is not in your best interests to continue. We will discuss any withdrawal decisions with you and provide health care advice where appropriate.

Other reasons that you may be withdrawn from the study are:

- The study is stopped
- You have a serious reaction, illness, or injury that is not related to the study.

Can I find out the results of the study?

Information relating to this study, such as a summary of results, will be available on the Australian New Zealand Clinical Trials Registry (ANZCTR).

You can choose to be sent a copy of the study results once the study is over. You can select this in the consent form below.

Who is funding the study?

This study is being funded by contestable grants.

You will not have rights to ownership or benefit financially.

Te Toka Tumai Auckland Hospital and the University of Auckland may receive payment from donor organisations for conducting this research. The study team members will only receive their ordinary wages for conducting this research.

Who has approved this study?

An independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards, has approved this study. The Central HDEC has approved this study.

Who do I contact for more information?

If you have any questions, concerns, or complaints about the study at any stage, you can contact:
Dr Jessica Dunning – Principal Investigator
butterfly@auckland.ac.nz
02885170054

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on:
Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Māori cultural support please contact:
He Kamaka Waiora (Māori Health Team)

butterfly@auckland.ac.nz
02885170054

You can also contact the health and disability ethics committee (HDEC) that approved this study on:
Phone: 0800 400 569 (Ministry of Health general inquiries)
Email: hdecs@health.govt.nz

APPENDIX 1 – PROCEDURE RISKS AND DISCOMFORTS

These are the standard risks that will be discussed for any laparoscopic resection of endometriosis, whether part of the study or not.

Laparoscopy Discussion Points & Risks:	Endometriosis Resection Discussion Points & Risks:
☐ Urinary catheter ☐ Use of uterine manipulator ± bowel probe ☐ Uterine perforation ☐ Conversion to laparotomy ☐ Bleeding (bruising / haematoma / haemorrhage) ☐ Haemostatic agent use / blood transfusion ☐ Injury to bowel / ureter / bladder / vessels / nerves ☐ Unplanned procedures (including removal of ovary / fallopian tube / appendix / bowel) ☐ Off-label medicine use (ICG, dye, vasopressin) ☐ Anti-adhesion fluid (Adept) ☐ Deep vein thrombosis / venous thromboembolism ☐ Wound issues (scaring, hernia, umbilical) & adhesions ☐ Infection (mild/severe) ☐ Pain / nausea / vomiting / voiding difficulty / constipation	☐ Injury to uterus / fallopian tubes / ovary ☐ Bowel resection ± stoma ☐ Effect on fertility / Ovarian reserve reduction ☐ Persistent pelvic pain ☐ Recurrence of endometriosis ☐ Mirena malposition / expulsion / removal difficulty All Procedures: ☐ Use of images / video for teaching ☐ Incomplete procedure / cancellation ☐ Readmission / return to theatre

APPENDIX 3 – CONTRACEPTION REQUIREMENTS

For participants who could become pregnant:

There are no contraception requirements for this study.