Endo Barostat Study - 2D

Project title: Determining the role of visceral hypersensitivity or chronic intestinal inflammation in the generation of GI symptoms in patients with endometriosis: A Pilot Study.

Project ID: 33011

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Associate Investigators: Professor Jane Fisher, Professor Mark Morrison, Dr Roni Ratner, Dr Judy Moore.

1. **Introduction:**

You are invited to take part in this research project. This is because you have been diagnosed with endometriosis and are experiencing gut symptoms that meet the criteria for irritable bowel syndrome (IBS).

This participant information and consent form tells you about the research project. It explains all that is involved. This will help you to decide if you want to take part in this research.

2. **What is the purpose of this research?**

Endometriosis is a common condition that affects more than 700,000 Australians. Many people have symptoms of chronic abdominal pain and bowel symptoms such as bloating, constipation or diarrhoea – typical symptoms of irritable bowel syndrome (IBS), and many of these people with endometriosis are also diagnosed with IBS. Both these conditions impact

significantly on a person's quality of life. It is often difficult distinguishing symptoms between the two conditions. At present we do not understand what causes these gastrointestinal symptoms in people with endometriosis. This study seeks to explore whether chronic inflammation caused by endometriosis and/or having a highly sensitive gut wall contributes to the gastrointestinal symptoms commonly experienced by women with endometriosis.

3. What does my participation involve?

Screening process and consent to participate (completed at home)
Initially, you will be required to complete a screening survey and/or have a conversation with the Study coordinator to determine your eligiblity to participate in this study.

If the screening survey or study coordinator determines that you are eligible to participate in this study, you will need to have an initial screening appointment (via Zoom) with the study doctor (Dr Rebecca Burgell) to confirm you are eligible to take part. This appointment will take ~30 minutes. The study doctor will ask you screening questions about your medical history, your surgical history and how your endometriosis was diagnosed. The study doctor will also check your general health and discuss the study in detail so that if you are eligible, you can decide whether you would like to participate. You are invited to ask any questions about the study at this appointment. If you are eligible and interested in participating you will need to complete an electronic consent form.

One-off questionnaire, stool and vaginal samples (collected at home)
Once you have completed your electronic consent form you will be emailed a link to the study questionnaire and posted kits (and instructions) for collecting stool and vaginal samples. The questionnaire + stool and vaginal samples can be collected from home in the days preceding your appointment at the Alfred for the rectal barostat and biopsy procedure (described below). The questionnaire is a one-off cluster questionnaire that takes ~30 minutes to complete and asks you questions about your gastrointestinal symptoms, your endometriosis, your quality of life and your mental health. The stool and vaginal samples will be analysed so we can see what kind of bacteria inhabit your vagina and gastrointestinal tract.

One-off rectal barostat and biopsy procedure (completed at the Alfred Hospital)
Participants will be required to fast overnight, then in the morning, attend the Gastrointestinal Physiology Laboratory at the Alfred Hospital to complete the rectal barostat procedure. The rectal barostat procedure is used to test how well you feel things in the rectum.

On arrival, you will be asked some questions about your gastrointestinal symptoms and bowel habits. If required, you may be given a water enema to clean out the lower part of your bowel. After you have emptied your bowel into the toilet, you will be asked to lie on your side with your legs bent. After a brief rectal examination, a thin tube with a bag attached will be eased gently into place inside your rectum.

- First, the bag will be inflated slowly with a little air and then deflated to ensure that it is lying correctly within the last part of the bowel.

- The sensation of the bowel will then be tested by a series tests where varying amount of air is put into the bag. This mimics what happens when you need to open your bowels. You will be given a keypad to register the sensations that you feel. If at any time during this procedure you experience an intolerable sensation, you can press a button and the inflations will stop, the bag will be deflated and the procedure will be terminated.
- Immediately following the barostat examination, 4 x rectal biopsies will be taken. A rectal biopsy is a procedure involving the removal of a small amount (~ 1mm) of tissue from the rectum. To perform this procedure a telescope is passed across the anal canal and special forceps are used to take a tiny piece of the lining of the bowel. The tissue is sent to pathology for testing. There may be some discomfort during the procedure. You may feel like you need to have a bowel movement. You may feel cramping or mild discomfort as the instrument is placed into the rectal area. You may feel a pinch when a biopsy is taken. There is a risk of infection, bleeding (which very rarely can be significant) or damage to the rectal mucosa or bowel wall from a rectal biopsy, but this is considered extremely low, less than 1 in 10,000 patients experience this problem. If this did occur, there may be a need for surgery to repair the area.

If an abnormality is found on either examination or on biopsy that could impact your health you will be contacted by the study team and follow up will be arranged through the Department of Gastroenterology at Alfred Health or an alternative clinician (depending on your preference)

We do not anticipate you will become upset or distressed as a result of your participation in the research. However, if you do, the medical team will arrange a referral to an external mental health care provider that is not part of the research project team. You may choose to access this through your GP where costs may be offset by the use of a mental healthcare plan that allows medicare reimbursement of costs". Alternatively, you can access one of the following services:

- Nurse on Call - A Victorian Government health initiative, is a phone service that provides immediate, health advice and information from a registered nurse, 24 hours a day, 7 days a week. Telephone 1300 606 024
- Beyond Blue offers access to information, resources and services www.beyondblue.org
- Lifeline - offers confidential counselling and referrals, 24 hours a day, 7 days a week. Telephone 13 11 14

4. Source of funding.

This research project is funded by a Medical Research Future Fund (MRFF) grant.

5. Consenting to participate in the project and withdrawing from the research

Participation in this research is voluntary. If you don't wish to take part you don't have to, and your decisions will not affect your relationship with Monash University in any way. If you decide you wish to take part, you will be asked to sign the electronic consent form. By signing this you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to complete the questionnaires, to collect the stool and vaginal samples and to undergo the rectal barostat and rectal biopsy procedures.
- Consent to the use of your personal and health information as described.

For your records, you will be provided a downloadable copy of the participant information sheet when you sign the consent form.

You may withdraw from this project at any stage. Please let the study coordinator know so she can discuss any issues that may arise from your withdrawing, and can answer any questions you may have. If you do withdraw your consent, no additional data will be asked of you. However, personal information already collected will be retained to ensure the results of the study are recorded properly and to comply with the law as we need to retain data to ensure correct reporting for the trial.

6. **Privacy and confidentiality**

REDcap is a forum for an online questionnaire that is totally confidential. Only persons licensed to access it can see your answers. These persons will be the study coordinator and the 2 chief investigators named above.

Any information obtained in connection with this research project that can identify you will remain confidential and securely stored. All data pertaining to you will be allocated a study number or code, which can be re-identified if needed at any stage of the study. It will be disclosed only with your permission, or as required by law. All data will be stored in a locked cabinet and/or password protected server (that only the listed investigators have access to) in the Department of Gastroenterology, Monash University. This information is stored for 7 years after publication of the results. After this time, hard copy documents will be shredded and digital data will be deleted.

All biopsies samples will be placed in formalin and processed for examination. Any tests on these samples will use study codes only. They will be destroyed after the customary 7 years for which study samples are held.

It is anticipated that the results of this research project will be published and/or presented in scientific seminars and conferences. In any publication or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Only combined data from which no individual can ever be identified will be published. You will be advised of the results of the research study when the data have been analysed and prepared for publication. This can take months to years after the project has finished.

7. **Complaints**:

Should you have any concerns or complaints about the conduct of this project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Chancellery Building D
26 Sports Walk, Clayton Campus
Research Office
Monash University VIC 3800
Tel: +61 3 9905 2052 Email: muhrec@monash.edu Fax: +61 3 9905 3831

Thank you,

Associate Professor Jane Muir; Associate Professor Rebecca Burgell, Dr Jane Varney

8. CONSENT:

Please tick the consent box if you wish to proceed

CONSENT BOX I understand the purpose of the study and what it involves for me. I am happy to complete the questionnaire, complete the pregnancy test, supply the stool and vaginal samples and undergo the rectal barostat and biopsy procedure as described. I know I can change my mind at any time if I don't wish to proceed. Please tick ✕

If you would prefer to sign a paper copy of the consent form, this will be posted/emailed to you by the study coordinator, Dr Jane Varney. Please discuss this form with someone you trust and have them witness your signing. Please return your paper consent from by post at the address below or scan and email it to me at jane.varney@monash.edu .

Dr Jane Varney
Level 6, The Alfred Centre,
Monash University
99 Commercial Rd,
Melbourne VIC 3004

After you have consented to this study, an email link to the study questionnaire will be sent to you, along with the stool and vaginal sample collection kits. In addition, an appointment will be made for you to attend the Gastrointestinal Physiology Laboratory at the Alfred Hospital to complete the rectal barostat and biopsy procedures.

Kind regards,

Dr Jane Varney
Study Coordinator

CONSENT FORM – printed version

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Declaration by Participant

- I have read the Participant Information Sheet and understand it.
- I understand the purposes of the questionnaires, and faecal and vaginal collection procedures described in the project.
- I understand data collected will be used for the purposes of this project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study.
- I understand that I will be given a signed copy of this document to keep.

I agree to all of the above:
× Yes
× No

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness to Participant's Signature (please print) _____

Signature _____ Date _____

Declaration by Researcher

I have given a verbal explanation of the research project; its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.