GYNAECOLOGY PLUS
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Native tissue repair with or without autologous blood graft augmentation for pelvic organ prolapse: A randomised controlled trial

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Site of Study:
FBW Gynaecology Plus
46 Marleston Ave
Ashford, SA 5035
08 8297 2822

Participant Information and consent

This study was developed for assessing a treatment option for women with pelvic organ prolapse. You have been approached about this study due to your diagnosis of pelvic organ prolapse.

The recommended treatment for pelvic organ prolapse is native tissue repair. The recurrence rate of prolapse in this standard surgery is high (up to 50%). Therefore, this study is designed to assess an experimental treatment for your situation in order to improve surgical outcomes and success of the treatment.

The experimental treatment introduced in this study is called **a blood graft made of your own blood (autologous graft).** This treatment is used or being tested in other areas of medicine, including musculoskeletal injury and cosmetic procedures. It will help tissue repair after the prolapse surgery with your own blood material.

The graft makes new cells and tissue and helps the strengthening of the repair attracting stem cells and growth factors to the surgical site. This aims to make the repair stronger.

To make this blood graft, your own blood is collected into a specially designed tube. Your blood sample will be processed in a sterile manner and the final product is a solid graft. At the end of the operation, this graft will be placed onto the underlying tissues. Simply put, the graft will attached to the repaired site.

The investigators will explain all process to you and address any questions you may have.

Invitation to participate:
We invite you to participate in this research project. Regardless of your decision, your medical care/relationship with your gynaecologist will not be affected.

Aims of the project:
The aim of this project is to determine whether the graft is safe, effective, and feasible in native tissue repair.

Assignment to a group:
If you decide to participate then you will be "randomised" into one of the groups described below. Randomisation means that you are put into a group by chance (like flipping a coin). You will have an equal chance of being placed in either group. Neither you nor your doctor can choose what group you will be in.

Group 1 (EXPERIMENTAL ARM): Surgery with autologous graft
If you are randomised to Group 1, you will have native tissue repair surgery for your vaginal prolapse. Immediately before surgery, the experimental treatment involves drawing up 40mls of your own blood for processing the autologous graft; this graft will be prepared and produced at the time of surgery and then be sutured or glued to the underlying connective tissue during prolapse surgery.

In the operating theatre room, you will be under a general anaesthesia during surgery. The conventional vaginal repair will be performed. Then the autologous graft will be placed onto the prolapse repair site for augmentation. The vaginal skin is closed after this layer. At completion of surgery, a vaginal pack and in-dwelling catheter will be placed until the next morning.

Group 2 (CONTROL ARM): Conventional prolapse repair surgery
If you are randomised to Group 2 you will be undergo the conventional prolapse repair surgery. The surgery will be the same as group 1, except that there is no graft created. At completion of surgery, a vaginal pack and in-dwelling catheter will be placed until the next morning.

In both groups, your postop care will be the same. Routine postoperative instructions will be provided to you including advice on physical activity progression, regular bowel habit, and abstinence of intercourse for 6wks. You will be discharged with an oral antibiotics if required. You will be followed up by our team by teleconsult at one week and face-to-face at 6 weeks, 6 months, and 12 months.

Summary of procedures:
Your invitation to this study means that a gynaecologist has already reviewed and diagnosed you with pelvic organ prolapse that requires pelvic floor repair surgery, because you have tried medications and non-surgical alternatives but still have prolapse symptoms. This is a randomised control study. If you choose to participate in this study, your participation will include the following:

A. **An initial assessment consultation**.
   - This will involve completing a questionnaire and undergoing a gynaecological examination, to assess and score the pelvic organ prolapse. A comprehensive medical history will be obtained from you. The date of surgery will be scheduled, and you will be guided to perform pre-op blood tests and other assessments as needed. This consultation takes 45-60 minutes.

B. A surgery procedure
   - The operation will be conducted at in an operating theatre under a general anaesthetic.

C. Three follow-up assessment consultations
   - The assessment consultations will involve collecting the same information as your initial assessment consultation – this will be the Australian Pelvic Floor Questionnaire and a gynaecological examination. This allows the investigators to compare information before and after your study treatment. These consultations take 30-45 minutes.
   - The second assessment is 6 weeks after your operation.
   - The third assessment is 6 months after your treatment.
   - The final assessment is 12 months after your treatment.

There will be two specialists involved in your care. The first specialist is the study doctor, who will administer the study treatment. The second specialist will be the assessing doctor at your follow-ups, who will perform the assessment.

There will be no medical expenses involved at any of these consultations or treatments. The dates for these appointments will be given to you at the initial consultation appointment.

The assessment consultations involve collecting information about your diagnosis and quality of life to determine whether the treatment has had any effect on your condition. Given your condition is of a gynaecological nature, this will involve personal questions relating to your prolapse, bowel, bladder and sexual function. Please discuss this with the study or assessing doctor if you have any concerns.

Commitments:
If you choose to be involved in this study, you will be asked to attend the hospital once for surgery and the gynaecology clinic four times over a 12-month period. These times will be arranged with you during your initial assessment consultation, and you will be given an appointment card with the dates.

Benefits:
During this study, your symptoms may remain the same, worsen, or improve. There is no guarantee that your symptoms will be alleviated with the experimental treatment.

What will happen to me at the end of the study?
After your last assessment consultation, you will have finished your role in this study. You may remain a patient of the study doctor and receive ongoing care from him/her in a normal medical relationship.

Risks:
The potential complications are related to the anaesthesia and surgery. The autologous graft is prepared from the whole blood of the patient so will be unlikely to induce an immune or allergic response. The possible surgery complications include pain, infection, bleeding, recurrence of prolapse symptoms, injury to uterus, and injury to surrounding structures, such as rectum and bladder. You are encouraged to discuss your concerns with the clinician if it does occur. Treatment will be offered for any adverse reaction. You will not incur any expenses should you require treatment for the adverse reaction.

Compensation:
You will not be charged for any of your treatment or assessments related to this study. However, you will be required to arrange your own traveling to your appointments as this is the routine follow-up after pelvic floor surgery.

If this study does not suit you emotionally or physically, you may withdraw from this study and your care will not be affected in any way. By participating in this study, you do not give up your legal rights.

If, as a result of your participation in this study, you become ill or are injured, immediately advise your study doctor of your condition. In the first instance, your study doctor will evaluate your condition and then discuss treatment with you and your regular treating doctor.

Any question about compensation should initially be directed to your study doctor who should advise their insurer of the matter. You may also seek independent legal advice.

Confidentiality:
All records containing personal information will remain confidential and no information which could lead to your identification will be released, except as required by law.

Your details will be de-identified. It will be recorded and stored in an electronic medical record and will not be destroyed. The data from this study will be coded and kept in an excel spreadsheet that is password protected. This spreadsheet will be located at the study site managed by the allocated research team.

Publication:
The de-identified information collected from you during this study will be used to assess whether the study treatment is better or worse than the current conventional treatment offered for your condition. The overall results of this study will be shared with the medical profession through scientific publications, presentations, and meetings. This information will not contain any information that may reveal your identity.

Withdrawal:
You may choose to withdraw from this study at any time. If you wish to withdraw, you can choose to remove any information collected on you. You can also choose to allow your data to remain in the study. Written consent will be obtained for the ongoing use of your data. Withdrawal from this study will not have any impact on your ongoing medical care with your doctor.

Outcomes:
If you wish, you can ask us to send you any publications we make on this project.

Contact:
If you would like more information about this project, please contact Dr Tran Nguyen or Dr Fariba Behnia-Willison at FBW Gynaecology Plus on 08 8297 2823.

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information, or complaints about the conduct of the study or your rights as a participant, you may contact the Committee chair, Bellberry Human Research Ethics Committee on 08 8361 3222.

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Consent for Participation in this Study

I ……the undersigned hereby voluntarily consent to my involvement in the research project titled: **An innovative autologous blood graft for native tissue vaginal repair augmentation compared to conventional surgery: A randomised controlled trial.**

I acknowledge that the nature, purpose and risks of the research project and alternatives to participation have been fully explained to my satisfaction by Dr ……

Specifically, the details of the procedure proposed and the anticipated length of time it will take, the frequency with which the procedure will be performed and an indication of any discomfort that may be expected have been explained to me.

I freely agree to participate in this research project according to the conditions in the Participant Information Sheet which I confirm has been provided to me.

I understand that my involvement in this study may not be of any direct benefit to me.

I have been given the opportunity to have a member of my family or another person present while the study is explained to me.

I have been told that no information regarding my medical history will be divulged to third parties and the result of any tests involving me will not be published so as to reveal my identity.

I understand that I am free to withdraw from the study at any stage without prejudice to future treatment. If I decide to withdraw from the study, I agree that the information collected about me up to this point when I withdraw may continue to be processed or excluded altogether.

I am 18 years of age or over.

I consent to my treating doctor/s being notified of my participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.

I declare that all my questions have been answered to my satisfaction.

I have read or have had read to me in a language in which I am fluent, and I understand the Participant Information Sheet.

Name of study participant: _____

Signature of study participant: _____ Date: _____

Declaration by senior researcher*:

A verbal explanation of the research project, its procedures and risks has been given to the participant and I believe that the participant has understood that explanation.

Name of senior researcher: _____

Signature of senior researcher: _____ Date: _____

* A senior member of the research team must provide the explanation and provision of information concerning the research project.