FAH018170

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Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

AUSTIN HEALTH

Title	Micronised progesterone for transfeminine individuals: a randomised, placebo-controlled cross-over trial
Short Title	Micronised progesterone for transfeminine individuals
Protocol Number	1
Principal Investigators	Dr Ada Cheung Dr Brendan Nolan
Location	Austin Health

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you identify as transfeminine. The research project is testing a new anti-androgen (testosterone blocker) treatment. The new treatment is called micronised progesterone.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Transfeminine individuals are commonly treated with estradiol and an anti-androgen (testosterone blocker) such as spironolactone or cyproterone acetate. There has been increasing anecdotal evidence about the potential benefits of micronised progesterone as a

testosterone blocker, with some women reporting improved breast development and reduced anxiety. However there has been no high-quality research evaluating these potential benefits.

Studies of micronised progesterone treatment in post-menopausal women have demonstrated improved sleep. Progesterone is known to reduce testosterone levels so represents an alternative treatment option as testosterone blocker.

In this project we will be replacing the usual testosterone blocker with micronised progesterone. We will aim to see if this improves sleep, anxiety or breast development.

This project may give important information about a way to improve the lives of transfeminine individuals and could result in an alternative treatment option as a testosterone blocker.

Medications, drugs and devices have to be approved for use by the Australian Federal Government. Micronised progesterone is approved in Australia to treat menstrual irregularities or as hormone replacement therapy.

This research has been initiated by the study doctor, Dr Cheung. The results of this research will be used by the study doctor, Dr Nolan to obtain a PhD.

3 What does participation in this research involve?

3.1 Study Design

You will be participating in a randomised controlled trial. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into two groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). You will have a one in two chance of receiving micronised progesterone followed by placebo and a one in two chance of receiving placebo followed by micronised progesterone. A placebo is a medication with no active ingredients without any medical benefit. It looks like the real thing but is not.

This is a double-blind study. This means that neither you nor your study doctor will know which treatment you are receiving. However, in certain circumstances your study doctor can find out which treatment you are receiving.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

3.2 Details of your involvement

We would need your agreement and signature on the consent form before doing any study assessments.

After this, the initial steps will take about 0.5 hours. These are:

- Interview. One of our doctors will ask about your medical history and the medications you are taking. We can get some of this information from your medical record.
- Blood test. These are normal blood tests involving a small needle in your arm. We are checking hormone levels (testosterone, estradiol), electrolytes (blood salts), liver function tests and full blood count. Even if you weren't in the trial, you would be having blood tests at this stage in your care. We will not be taking any additional blood tests.

We will review the results of these assessments to make sure that there isn't a problem with you participating in the trial. Certain medical conditions mean that we would not be able to include you. If you are not eligible to be in the trial, you will still continue to be seen by your usual doctor.

If you were eligible, then your first study assessments would take place. The time commitment would be approximately 1 hour.

- Questionnaires. These will ask you about your sleep, anxiety and breast development.
- Blood test (total 9mL or 2 teaspoons).

Next you will either commence treatment with micronised progesterone or placebo.

After 28 days, the second study visit and assessments will occur. This will take about 1 hour of your time and will involve repeating some of the tests above. There are no new tests (the questionnaires and blood tests are the same as the ones before).

- Questionnaires.
- Blood test (total 9mL or 2 teaspoons).

After 56 days, the final study visit and assessments will occur. This will take about 1 hour of your time and will involve repeating some of the tests above. There are no new tests (the questionnaires and blood tests are the same as the ones before).

- Questionnaires.
- Blood test (total 9mL or 2 teaspoons).

3.3 Summary of study visits

Visit	Timing	Assessments	Duration
Screening	After you consent.	Interview Blood test Questionnaires	1 hour
1	After 28 days.	Blood Pressure Height, Weight Questionnaires	1 hour
2	After 56 days.	Blood Pressure Height, Weight Questionnaires Blood test	1 hour

3.4 Costs and reimbursement

There are no additional costs associated with participating in this research project, nor will you be paid. Study visits will be organised in conjunction with your usual clinic visits to minimise disruption and costs associated with being involved in the research project.

3.5 How this research will be monitored

To protect participants, this study is continually monitored by an external Data Safety Monitoring Board that is independent of the researchers. The Board has the power to stop the trial if it was concerned about a matter of safety.

3.6 Your local doctor

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 What do I have to do?

To participate in this study you will need to take the micronised progesterone capsule every night or continue your usual testosterone blocker according to the instructions provided. This is very important for the outcome of the study. Apart from attending the study visits for the assessments outlined above, there are no lifestyle or dietary restrictions. You will be able to donate blood if you are already a blood donor.

You will continue to take all your regular medications. Please notify the study doctor if there are any change to your medications during the study period. We won't prevent you from taking any medications that you need for your medical care.

5 Other relevant information about the research project

This project is organised through Austin Health. 38 participants will be taking part in this research study. Of these, half will be treated with micronised progesterone followed by placebo and the other half will be treated with placebo followed by micronised progesterone.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, your will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Austin Health.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include testosterone blockers such as spironolactone or cyproterone acetate. This research project is trialling an unproven therapy in addition to usual care. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include improved sleep, reduced anxiety or enhanced breast development.

9 What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor

may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

9.1 Possible risks associated with taking micronised progesterone

We are using a product called Prometrium (micronised progesterone) that is approved by the Australian Therapeutics Goods Administration (TGA) for use in women to treat menopausal symptoms. Until now, it has had no use in transfeminine individuals and so this product has not been put before the TGA for approval for this use. We are using the lowest dose of progesterone to minimise potential side effects.

Possible side effects from micronised progesterone are:

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Dizziness and/or drowsiness	<1 in 100 (1%)	Variable but serious cases have been reported. The capsule is taken before bed to reduce these risks.	Would resolve within days of cessation.
Fluid retention	Common. 6 in 100 (6%)	May cause mild leg swelling or elevate blood pressure. Both would be easily treatable.	Would resolve within days of cessation.

Any side effects from this treatment would be managed as part of your normal care at Austin Health. If you elect to be treated as a public patient this would be free of charge.

9.2 Risks associated with blood tests

Having blood taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

9.3 Risk of psychological distress

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my test samples?

A mandatory part of participation in this study is the collection of blood samples. All blood samples are those that are taken as part of routine clinical care. We will not be taking any additional blood samples.

Most of your blood samples will be analysed by the Austin Pathology Laboratory and then your sample will be discarded within 14 days. These results will go onto your medical file and also be recorded for this study. We will not be storing blood for future use.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The drug being shown not to be effective
- The drug being shown to work and not need further testing
- Decisions made by local regulatory/health authorities.

15 What happens when the research project ends?

For each participant, this study runs for 3 months but it will take us about 12 months to recruit all the women we need for the trial. After your 3 months you can stop taking the progesterone and continue your previous treatment. You will continue to have ongoing treatment by your Endocrinologist.

About 3 months after the last women have gone through the study, we will send you a letter to explain what the results were. You will be welcome to phone us to discuss these or to discuss them when you are next reviewed by your Endocrinologist.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Only the

researchers named above will have access to it. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. Information on paper will be stored in a locked filing cabinet within a locked office located at Austin Health. Your information will be stored in a folder that will contain a study number and not your name. The code to match up names with study numbers will be kept electronically. Electronic information such as this will be stored on a password protected computer system on a server at Austin Health. Your paper and electronic data will be stored for 15 years following the completion of this study. At the end of 15 years, the information that is purely for this study (i.e. that does not also form part of your Austin Health medical record) will be permanently destroyed (deleted or shredded).

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project. Information about your participation in this research project will be recorded in your health records.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. This is because results will be published in aggregate only and include no features that could identify any individual participant.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

17 Complaints and compensation

17.1 Complaints

If you have a complaint about any aspect of your medical care or treatment at Austin Health please raise this with your doctor directly. If this is not possible or does not resolve the complaint then the Centre for Patient Experience will help you. You can speak to a consumer liaison officer at the Centre for Patient Experience by calling (03) 9496 3566.

17.2 Treatment Available

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

17.3 Compensation

In the unlikely event that you suffer an injury as a result of participating in this trial, hospital care and treatment will be provided by the public health service at no extra cost to you.

Neither the hospital nor the investigators guarantee that compensation for other loss or injury will be available to you (such as loss of income from work days missed or health care costs not covered by public health services). However, by signing the consent form, you have not waived any legal or other right to seek compensation, including legal rights for negligence or other causes of action.

18 Who is organising and funding the research?

The names of the researchers are listed at the top of the first page. All of the researchers except work at Austin Health. Dr Cheung and Dr Nolan designed the study. Dr Cheung is in charge overall. Dr Nolan is an Endocrinologist at Austin Health and PhD candidate at the University of Melbourne. This study will form part of his PhD thesis and he will be responsible for the day-to-day running of the study.

This study has been approved by Austin Health. Funding for the study comes from a grant to Dr Cheung from the Endocrine Society of Australia.

18.1 Financial benefit from this research

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to Austin Health.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Austin Health, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

18.2 Declarations of interests of researchers

- Dr Ada Cheung: none.
- Dr Brendan Nolan: none.

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Austin Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems that may be related to your involvement in the project (for example, any side effects), you can contact:

Clinical contact person 1

Name	Dr Brendan Nolan
Position	Co-Principal Investigator
Telephone	03 9496 2975 (in hours) 03 9496 5000 (after hours)
Email	bjnolan@student.unimelb.edu.au

Clinical contact person 2

Name	Dr Ada Cheung
Position	Co-Principal Investigator and Head of Gender Clinic

Telephone	03 9496 5000
Email	adac@unimelb.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Complaints contact person

Name	Complaints contact person
Position	Office for Research
Telephone	03 9496 3248
Email	ethics@austin.org.au

If you need to contact the Human Research Ethics Committee that approved this project, then you may contact:

Reviewing HREC and HREC Executive Officer

Reviewing HREC name	Austin Health Human Research Ethics Committee
HREC Executive Officer	Chelsea Webster
Telephone	03 9496 3248
Email	ethics@austin.org.au

Consent Form - *Adult providing own consent*

Title	Micronised progesterone for transfeminine individuals: a randomised, placebo-controlled cross-over trial
Short Title	Micronised progesterone for transfeminine individuals
Protocol Number	1
Principal Investigators	Dr Ada Cheung Dr Brendan Nolan
Location	Austin Health

Consent Agreement

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Austin Health concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Witness to the informed consent process
Name (please print) _____

Signature _____ Date _____

* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

Declaration by Study Doctor/Senior 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 Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

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

Form for Withdrawal of Participation - *Adult providing own consent*

Title	Micronised progesterone for transfeminine individuals: a randomised, placebo-controlled cross-over trial
Short Title	Micronised progesterone for transfeminine individuals
Protocol Number	1
Principal Investigators	Dr Ada Cheung Dr Brendan Nolan
Location	Austin Health

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Austin Health.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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