



## 'A randomised double-blind trial comparing the effectiveness of anti-androgen medications in trans and gender diverse individuals'

**This study has been approved by the Austin Health Human Research Ethics Committee: HREC/44503/Austin-2018**

### **What is the study looking at?**

Transfeminine individuals desiring hormone therapy are typically treated with an estrogen (estradiol) and an anti-androgen (also known as testosterone blocker, e.g. spironolactone or cyproterone acetate) to achieve changes such as breast growth, body fat redistribution and a reduction in facial and body hair. This study is looking at which anti-androgen is better at causing feminisation.

### **Can I participate in this study?**

We are looking for people aged 16 – 80 years who are about to commence hormone therapy with estrogen and an anti-androgen.

You may be ineligible to participate if you have a history of:

- Heart, liver or kidney disease
- Severe depression
- High potassium levels
- Blood clots in the legs or lungs (e.g. deep vein thrombosis, pulmonary embolism)
- Estrogen sensitive cancer (e.g. breast cancer)
- Meningioma (brain tumour)
- Planned removal of testes (orchidectomy) during the study period (6 months)

### **What does it involve?**

To take part, you need to be able to attend five (5) study visits at the Heidelberg Repatriation Hospital over a 6 month period.

Each visit may involve the following:

- Medical history and examination by study doctor/nurse
- Blood test
- Completion of depression and gender dysphoria questionnaire
- ECG (tracing of heart electrical activity)
- DXA (a very low radiation scan used to measure your body composition)
- Chest photography (photos using specialised camera taken from the front and side to work out the volume of your breasts)



Visit	Timeframe	Preparation	What to expect	Duration
1	First visit	<ul style="list-style-type: none"><li>• Complete 2 questionnaires before appointment</li><li>• Arrive fasting for blood test</li></ul>	Blood test Medical history and examination ECG Chest photography DXA scan	Allow 2 hours
2	1 month	<ul style="list-style-type: none"><li>• Arrive fasting for blood test</li></ul>	Blood test	Allow 20 mins
3	2 months	<ul style="list-style-type: none"><li>• Arrive fasting for blood test</li></ul>	Blood test	Allow 20 mins
4	3 months	<ul style="list-style-type: none"><li>• Complete 2 questionnaires before appointment</li><li>• Arrive fasting for blood test</li></ul>	Blood test Medical history and examination	Allow 1 hour
5	6 months	<ul style="list-style-type: none"><li>• Arrive fasting for blood test</li></ul>	Blood test Medical history and examination ECG Chest photography DXA scan	Allow 2 hours

### What will I get out of it?

By volunteering your time, you will be contributing to research that will allow us to better understand the changes that occur during gender-affirming hormone therapy. The results will guide us in providing more effective and safer treatments. You will also learn about what is happening to your body, and you will have access to all results.

You will be provided with anti-androgen medication at no cost for the duration of the study.

You will receive copies of all your test results, which you can keep for your records or share with your healthcare professional.

### When will I be seen?

It is important that the first visit occurs before or soon after you start taking hormone therapy, so that the baseline blood tests, photos and DXA scans are reliable.

### Where is the study?

Study visits will occur at the Endocrinology Unit at the Heidelberg Repatriation Hospital, 300 Waterdale Rd, Heidelberg West. Further instructions will be provided if you would like to participate in the study.



### What information do I need to provide?

If you would like to participate, please provide us with the following:

- Legal name
- Preferred name and pronouns
- Date of birth
- Postal address
- Contact number
- Email address
- Medicare number, reference and expiry
- GP name and contact details
- Emergency contact details
- List of medical conditions, e.g. heart, kidney, liver problems, depression, blood clots
- List of current medications
- Preferred days to attend appointments (Study visits are generally done in the mornings before 10am on weekdays)
- Height and weight

If you have any questions or would like to participate in the study, please contact us:

**Dr Lachlan Angus** MBBS

Consultant Endocrinologist | PhD Candidate

Department of Medicine (Austin Health) | The University of Melbourne

T: 0451 661 295; F 9496 2980

E: [anti-androgen@unimelb.edu.au](mailto:anti-androgen@unimelb.edu.au)