The influence of testosterone administration on pelvic organ changes and sexual functioning in transmasculine and gender-diverse persons: a quantitative assessment using magnetic resonance imaging

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Ethical review	Approved WMO
Status	Pending
Health condition type	Sexual function and fertility disorders
Study type	Observational non invasive

Summary

ID

NL-OMON57385

Source
ToetsingOnline

Brief title
IMPAC-T (Imaging Morphologic Pelvic Anatomy Changes due to Testosterone)

Condition

- Sexual function and fertility disorders

Synonym
sexual (dys)function, sexual (dys)functioning

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: European Society for Sexual Medicine Research Grant (grant number RG24-03)

Intervention

Keyword: Clitoris, Pelvic floor, Testosterone, Transmasculine

Outcome measures

Primary outcome

The primary endpoints are clitoral and pelvic floor musculature volume (expressed in mm3) and the percentage changes in volume (expressed in %) between measurements prior to starting testosterone administration and after nine months of treatment in transmasculine and gender-diverse persons.

Secondary outcome

Secondary endpoints are pelvic floor musculature volume and clitoral volume (expressed in mm3) and percentage changes in clitoral volume (expressed in %) during audiovisual sexual stimulation, self-reported feelings of sexual arousal during audiovisual sexual stimulation, and sexual function assessed by an adapted sexual function questionnaire.

Study description

Background summary

Gender-affirming hormone therapy for transmasculine and gender-diverse (TMGD) persons assigned female at birth typically involves testosterone administration to align physical traits with gender identity. Testosterone induces notable changes in the pelvic and genital area, causing alterations in genital

microvasculature and sexual response. Clitoral hypertrophy is a frequently-mentioned effect, but while external growth of the clitoris is reported, no studies have quantified internal clitoral growth or its relationship with androgens and sexual function. In addition to changes in the clitoris, recent literature indicates that over 60% of TMGD persons experience pelvic pain during sexual activity, with another study exploring a possible link with changes in the pelvic floor musculature, which is known to be androgen-sensitive. Again, the relation with sexual functioning is unclear.

Study objective

This study aims to be the first to visualise changes in both clitoris and pelvic floor musculature following testosterone administration and to explore how these changes relate to sexual function. The primary objective of this observational study is to examine clitoral and pelvic floor musculature volume and percentage changes in volume in transmasculine and gender-diverse persons prior to start of testosterone administration and after nine months of treatment. The secondary objectives are to examine pelvic floor musculature and clitoral volume and percentage changes in clitoral volume during audiovisual sexual stimulus and to explore the association between self-reported sexual function and changes in clitoral and pelvic floor musculature volume.

Study design

This is an observational cohort pre-post study with non-invasive measurements. Participants will complete questionnaires and undergo magnetic resonance imaging (MRI) during two visits to Amsterdam UMC, location AMC. During these visits, they will view a neutral and an erotic film segment while the MRI measurements are taken.

Study burden and risks

As this study will provide important insights into the anatomical and functional changes experienced by TMGD individuals initiating testosterone therapy, successful completion will definitely have an impact within the fields of sexual medicine and gender-diverse healthcare. Specifically, it will give information on how testosterone affects both external and internal clitoral structures, as well as the pelvic floor musculature. By using dynamic MRI to visualize these changes (in response to sexual stimuli), we aim to fill gaps in the knowledge on physiological changes associated with testosterone. The risks associated with this study are small: they are related to possible intruding questions and discomfort associated with genital MRI testing; through extensive selection and preparation beforehand, chances of this research triggering feelings of dysphoria will be kept at a minimal.
MRI itself is a non-invasive imaging modality. All participants will receive extensive information about the MRI procedures and will be screened on

contra-indications beforehand. There will be minor discomfort caused by having to lie still for several minutes and being fixed in a small space. Subjects suffering from claustrophobia are therefore excluded from participation. Considering the coaching and preparation beforehand, we consider the burden of this procedure to be minimal. Since MR imaging is considered a safe standard medical procedure, we evaluate the risks associated with MR scanning to be negligible.
Altogether, this pilot study can offer data to healthcare providers that can help them manage expectations and addressing sexual dysfunction in TMGD individuals. As improved understanding of pelvic anatomical changes will lead to more personalized care and more successful targeted interventions, it can improve patient outcomes. Moreover, the study can serve as the foundation for future research on sexual wellbeing in TMGD individuals. This is all the more important within a minority community where existing data is sparse, while the need for more knowledge is highly present in clinicians and patients alike.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a participant must meet all of the following criteria:
• Transmasculine or gender-diverse persons assigned female at birth diagnosed with gender dysphoria;
• Age >18 years;
• Scheduled to begin testosterone treatment within one to three months;
• Ability to provide written consent.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
• Medical or mental conditions (acute or chronic) affecting genital response;
• History of hysterectomy, vaginal surgery, gynaecologic disease or malignancy, pelvic inflammatory disease, vaginal infection, or anatomical variations such as intersex conditions;
• Current pregnancy or recent delivery within the last 12 months;
• Self-reported genital dysphoria to the extent that participation is undesirable.
• Contraindications to MRI, including pacemakers, metal implants, or severe claustrophobia.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-05-2025

Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO Date:	14-03-2025
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL88599.018.24