Onderzoek naar het effect van hormoonbehandeling op de eierstokken

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27300

Source
NTR

Health condition

Androgens, ovaries, female-to-male transsexuals

Sponsors and support

Primary sponsor: VU University Medical Center, Amsterdam the Netherlands. Department of Obstetrics and Gynaecology in collaboration with the department of Gender Dysphoria of the VU University Medical Center.
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Gynaecology (SWOG)

Intervention

Outcome measures

Primary outcome

Ovarian morphology, in terms of:

- transvaginal ultrasound

- histopathological features

Secondary outcome

Predisposition towards hyperandrogenism and reproductive alterations in gender dysphoric (GD) individuals, and are polycystic ovaries more likely in GD females?

Study description

Background summary

Prospective observational cohort study.

The aim of this study is to examine the ovarian effects of long-term androgen treatment in gender dysphoric females. This will enable us to provide: 1. adequate care for FtMs concerning their inner genitalia, especially ovaries and 2. provide more insight in the pathophysiologic mechanism of PCOS. Standard androgenic treatment or surgery as part of their sex-reassigment hormonal therapy will not be influenced. Morphologic changes of ovaries will be determined by transvaginal ultrasound and histopathology.

Study objective

Long term androgen treatment in female-to-male transsexuals (FtMs) leads to changes in the ovaries: polycystic ovaries, determined by transvaginal ultrasound and histopathology.

So the aim of this study is to determine wether long-term high doses of exogenous androgens affect ovarian morphology. In terms of: 1. transvaginal ultrasound and 2. histopathological features.

Study design

T = 0: start androgenic treatment

T = 1: operation day (minimum of 12 months after start treatment)

Intervention

Standard androgenic treatment as part of their sex-reassignment hormonal therapy.

Contacts

Public
Arts-onderzoeker
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Eligibility criteria

Inclusion criteria

- Diagnosis Gender Dysphoria

- >1 year cross-sex hormonal treatment

- Age 18+

- Intention to undergo sex-reassignment surgery

Exclusion criteria

- Disorder of sexual development

- Concomitant pathology with known or possible endocrine effects

- Excessive alcohol or drug abuses

- Patients who explicitly declare that they do not want to participate in the study

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-08-2014
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-09-2014
Application type:	First submission

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
NTR-new	NL4632
NTR-old	NTR4784
Other	METC VUmc : 2014.402

Study results

Summary results
na.