Progesterone for Breast Development in Trans Women; Assessment of effects and safety -a pilot trial-

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To explore the effects on breast development of addition of progesterone to the treatment with estradiol in trans women after vaginoplasty or orchiectomy. Secondary objectives include safety and patient satisfaction, mood, and sleep.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Endocrine disorders of gonadal function
Study type	Interventional

Summary

ID

NL-OMON49293

Source
ToetsingOnline

Brief title
Progesterone in Trans Women

Condition

- Endocrine disorders of gonadal function
- Menopause related conditions

Synonym
gender affirming hormone treatment, Hypogonadism

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Besins Healthcare

Intervention

Keyword: Breast development, Estradiol, Progesterone, Transgender

Outcome measures

Primary outcome

The main study parameters include change in breast size as determined by

measurement of breast volume and determination of the bra cup size.

Secondary outcome

Serum progesterone levels, patient satisfaction, mood changes, sleep quality,

and adverse events are secondary endpoints.

Study description

Background summary

Trans women (male sex assigned at birth, female gender identity) receive hormone therapy in order to induce secondary female sex characteristics. Traditionally, this hormone therapy includes estradiol and anti-androgenic treatment. Research has demonstrated that breast de-velopment in trans women is often limited and as a result trans women may choose to un-dergo breast augmentation surgery. Progesterone is important for breast development in cis women (female sex assigned at birth, female gender identity) during puberty. A potential role for progesterone with regard to breast development in trans women has not been investigated in a controlled experimental set up.

Study objective

To explore the effects on breast development of addition of progesterone to the treatment with estradiol in trans women after vaginoplasty or orchiectomy. Secondary objectives include safety and patient satisfaction, mood, and sleep.

Study design

This is a non-blinded, non-placebo, randomized controlled pilot trial using a factorial design.

Intervention

Participants will be randomized into six groups of 15 subjects each (A-F). For 12 months, group A will continue to receive the baseline dose of estradiol (control group), group B will receive the baseline dose of estradiol and progesterone 200 mg daily, group C receive the baseline dose of estradiol and progesterone 400 mg daily, group D will receive twice the baseline dose of estradiol, group E will receive twice the baseline dose of estradiol and progesterone 200 mg daily and group F will receive twice the baseline dose of estradiol and progesterone 400 mg daily.

Study burden and risks

Participation in the study will include 4 visits to the clinic, at baseline (visit 1) and after 3, 6, and 12 months (visits 2,3,4). During visits 1-4, measurement of breast-chest circumference difference and volume measurement will be performed using breast 3D imaging. Participants will be asked to fill out questionnaires at visits 1-4. At visits 1, 3, and 4, blood samples will be taken. During the study, participants will continue their regular visits to the gender clinic. We estimate that the risks associated with the investigational treatment will be limited. Increased doses of estradiol may lead to breast pain, headache or weight gain. The most common side effect of progesterone is headache. Uncommon and rare side effects include breast pain, drowsiness, nausea, diarrhea, constipation, jaundice, pruritus, and acne. Increased risks of breast cancer, thromboembolic events, coronary artery disease, and ischemic stroke have been reported for progesterone-like compounds, but for not progesterone itself, when used in combination with estradiol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Start of hormone treatment after 18 years of age
- More than one year of hormone treatment
- Underwent vaginoplasty or orchiectomy
- Sufficient knowledge of the Dutch language
- BMI 18-30 kg/m2

Exclusion criteria

- No regular follow-up visits at the clinic for gender dysphoria
- Previous use of progesterone/ progestin (not including cyproterone acetate)
- History of breast augmentation or reduction surgery
- Active treatment for depression
- Current use of progesterone/ progestin including cyproterone acetate (e.g. because of increased bodily hair growth after vaginoplasty)
- Severe familial dyslipidemia (e.g. Familial Hypercholesterolemia)
- Serum estradiol concentration > VUmc reference range (150-400 pmol/L) at last visit prior to baseline
- Any of the following contraindications for the use of progesterone (Utrogestan): Known, past or suspected breast cancer; Known or suspected estrogen-dependent malignant tumours (e.g genital tract carcinoma); Thrombophlebitis; Previous or cur-rent thromboembolism disorders (e.g. deep venous thrombosis, pulmonary embo-lism); Known thrombophilic disorders; Acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal (<2.5xULN); Known hy-persensitivity to the active substances or to any of the excipients (Sunflower oil, Soya lecithin, Gelatin, Glycerol, Titanium dioxide); Porphyria; Cerebral hemorrhage.
- Mental health issues that prevent participation

- History of epilepsy

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-03-2021
Enrollment:	90
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lenzetto spray
Generic name:	Estradiol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Progynova
Generic name:	Estradiol valerate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Sandoz patch
Generic name:	Estradiol
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Systen patch
Generic name:	Estradiol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Utrogestan
Generic name:	Progesterone
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	07-12-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-01-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	24-07-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2024
Application type:	Amendment
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

ID: 21386
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2020-001952-16-NL
CCMO	NL73840.029.20
OMON	NL-OMON21386