Progesterone for Breast Development in Trans Women

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Exploratory. 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	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21386

Source
NTR

Brief title
PTW

Health condition

Hormone treatment to induce breast development in trans women

Sponsors and support

Primary sponsor: Amsterdam UMC, location VUmc
Source(s) of monetary or material Support: Besins Healthcare

Intervention

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

Rationale: 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 development in trans women is often limited and as a result trans women may choose to undergo 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. 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 objec-tives 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. Study population: Adult trans women who have undergone hormone treatment for at least one year, who underwent vaginoplasty or orchiectomy, and do not use cyproterone acetate are eligible for this study. People are excluded in case of mental health disabilities that pre-vent participation, insufficient knowledge of the Dutch language, increased thromboembolic risk or after breast augmentation or reduction surgery. 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. Main study parameters/endpoints: The main study parameters include change in breast size as determined by measurement of breast volume and determination of the bra cup size. Serum progesterone levels, patient satisfaction, mood changes, sleep quality, and adverse events are secondary endpoints. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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 im-aging. 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 tenderness, headache or weight gain. The most common side effect of progesterone is headache. Uncommon and rare side effects include breast tenderness, drowsiness, nausea, diarrhea, constipation, jaundice, pruri-tus, and acne. Increased risks of breast cancer, thromboembolic events, coronary artery disease, and ischemic stroke have been reported for progesterone-like compounds, but not for progesterone itself, when used in combination with estradiol.

Study objective

Exploratory. 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

6 months, interim analysis; 12 months, final analysis

Intervention

Addition of progesterone to the treatment with estradiol in trans women after vaginoplasty or orchiectomy

Contacts

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Eligibility criteria

Inclusion criteria

- Trans woman - 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 micronized progesterone (Utro-gestan): Known, past or suspected breast cancer; Known or suspected estrogen-dependent malignant tumours (e.g genital tract carcinoma); Thrombophlebitis; Previous or current thromboembolism disorders (e.g. deep venous thrombosis, pul-monary embolism); 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 hypersensitivity to the active substances or to any of the excipients (Sunflower oil, Soya lecithin, Gelatin, Glycerol, Titanium dioxide); Porphyria; Cerebral hemor-rhage. Interfering medication (SPC). - Mental health issues that prevent participation - History of epilepsy

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-01-2021
Enrollment:	90
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
NA

Ethics review

Positive opinion
Date: 02-12-2020
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49293
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9086
CCMO	NL73840.029.20
OMON	NL-OMON49293

Study results

Summary results
NA