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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21386

Bron
Nationaal Trial Register

Verkorte titel
PTW

Aandoening

Hormone treatment to induce breast development in trans women

Ondersteuning

Primaire sponsor: Amsterdam UMC, location VUmc
Overige ondersteuning: Besins Healthcare

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameters include change in breast size as determined by measurement of breast volume and determination of the bra cup size.

Toelichting onderzoek

Achtergrond van het onderzoek

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 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.

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 prevent 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 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 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.

Doel van het onderzoek

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.

Onderzoeksopzet

6 months, interim analysis; 12 months, final analysis

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd

Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	03-01-2021
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
NA

Ethische beoordeling

Positief advies

Datum:	02-12-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49293
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9086

Register	ID
CCMO	NL73840.029.20
OMON	NL-OMON49293

Resultaten

Samenvatting resultaten
NA