The effects of sex hormone administration on marrow and visceral adiposity

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We hypothesize that suppression of the gonadal axis will increase bone marrow and visceral fat in biological women and men and subsequent administration of estradiol or testosterone will decrease the amount of bone marrow and visceral fat. We...

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

Samenvatting

ID

NL-OMON25190

Bron
Nationaal Trial Register

Verkorte titel
SHAMVA

Aandoening

No diseases are being studied. Amount of bone marrow and visceral fat, thrombocyte function.

Ondersteuning

Primaire sponsor: Amsterdam UMC, location VUmc
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Changes in vertebral marrow fat fraction measured by MRI quantitative chemical shift imaging (QCSI), changes in visceral fat, measured by MRI and DXA.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Marrow adipose tissue (MAT) is a unique fat depot, different from white and brown fat. The inverse relationship between MAT and bone mass, has led to the paradigm that MAT is a negative regulator of bone mass. MAT increases with ageing and men have more MAT than women below the age of 50 years. After menopause MAT becomes higher in women than in men. Together these data suggest that sex hormones are important regulators of MAT. Another fat depot with a comparable association with sex hormones is visceral adipose tissue (VAT). Men are more susceptible to VAT accumulation than premenopausal women, however VAT also increases in postmenopausal women. Understanding of VAT regulation is important because it is associated with cardiometabolic risks. Finally, epidemiological studies have shown that premenopausal women are relatively protected against cardiovascular disease, whereas after menopause the incidence seems to catch up with that of males. Although much is known about the influence of estradiol on plasmatic coagulation, much less is known about its influence on platelet function, the latter being of far greater importance in arterial CVD.

Objective: To determine the effect of sex hormones on bone marrow fat, visceral fat, and thrombocytes.

Study population: Adults with gender dysphoria, transwomen (before males-to-females) and transmen (before female-to-males), starting gender affirming hormone treatment in the Center of Expertise in the Amsterdam UMC, location VUmc. We will include 24 transmen and 16 transwomen.

Doel van het onderzoek

We hypothesize that suppression of the gonadal axis will increase bone marrow and visceral fat in biological women and men and subsequent administration of estradiol or testosterone will decrease the amount of bone marrow and visceral fat. We hypothesize that inhibition of conversion of testosterone to estradiol will attenuate the effect of testosterone on marrow and visceral fat.

Onderzoeksopzet

baseline, week 6, week 8, week 18, week 58

Onderzoeksproduct en/of interventie

Transwomen will receive a GnRH analogue every 4 weeks from week 0 until week 20 and estradiol from week 6 and cyproterone acetate from week 20 until the end of the study (week 58). Transmen will receive GnRH analogue every 4 weeks from week 0 until week 20, transmen will be randomized to receive either testosterone from week 6 until the end of the study or receive testosterone and an aromatase inhibitor from week 6 until week 18.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

 Diagnosed with gender dysphoria according to DSM V (female-to-male or male-to-female)
 Age between 18 and 50 years
 Female-to-male transgenders need to be premenopausal
 Starting cross-sex hormone treatment

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

 Previous use of cross-sex hormones
 Contraindications to MRI scanning
 Participation in other studies (with exception of the ENIGI study)
 Use of bone-modifying or adipose tissue-modifying drugs, current or in history

(bisphosphonates, estrogen receptor modulators, calcium regulating agents, corticosteroids)
 Bone or bone marrow diseases, current or in history (metabolic, malignancy, infectious, mechanic, bone marrow diseases)
 Platelet count <120*109/l
 History of non-traumatic major bleeding
 Known bleeding diathesis
 Conditions which require antiplatelet therapy
 Usage of antiplatelet therapy
 Chronic usage of medication known to influence platelet function (e.g. DOAC’s, NSAIDs, warfarin)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	14-02-2019
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-02-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7513
Ander register	METc VUmc : METc 2017.559, NL63784.029.17

Resultaten