The effects of sex hormone administration on marrow and visceral adiposity

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25190

Source
Nationaal Trial Register

Brief title
SHAMVA

Health condition

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

Sponsors and support

Primary sponsor: Amsterdam UMC, location VUmc
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

 Bone turnover markers (Ctx, P1NP, osteocalcin)
 Adiponectin and leptin.
 Changes in inflammation markers (HsCRP, IL-6, G-CSF)
 Changes in platelet activation, measured by PFA Closure Time, PFA Total Volume, PFA Initial Flow Rate, Plasma Thromboxane B2, Flow-cytometry among which p-selectin

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

 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

Exclusion criteria

 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)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-02-2019
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-02-2019
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	NL7513
Other	METc VUmc : METc 2017.559, NL63784.029.17

Study results