Kidney FuNction in people receiving Gender affirming Hormone Therapy

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Sex differences in renal physiology is a vastly understudied area, despite known differences in sex-specific rates of chronic kidney disease. Renal function decline is accelerated in men compared to women, suggesting a potential harmful role for…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23894

Bron
Nationaal Trial Register

Verkorte titel
KNIGHT-study

Aandoening

Research in renal physiology

Ondersteuning

Primaire sponsor: Dr. D.H. van Raalte Department of Endocrinology, VUMC/AMC De Boelelaan 1117, 1081 HV, Amsterdam E-mail: d.vanraalte@amsterdamumc.nl
Overige ondersteuning: scholarships and professional fees

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameters/endpoints are the measurement of glomerular filtration rate

(GFR) and effective renal plasma flow (ERPF) as measured by iohexol and p-amminohippurate (PAH) clearance.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Sex differences in renal physiology is a vastly understudied area, despite known differences in sex-specific rates of chronic kidney disease. Renal function decline is accelerated in men compared to women, suggesting a potential harmful role for testosterone. Transgender individuals undergoing hormone therapy provide a unique model to study the effects of gender affirming hormone therapy on kidney function and renal physiology.
Objective: The central objectives of this study are to comprehensively detail (intra)renal hemodynamic function and tubular function in transgender individuals before and after gender affirming hormone therapy.
Study design: Prospective observational study
Study population: Transgender individuals (20 transmen and 20 transwomen) between 18-30 years old, scheduled to start hormone therapy.
Intervention (if applicable): n/a
Main study parameters/endpoints: The main study parameters/endpoints are the measurement of glomerular filtration rate (GFR) and effective renal plasma flow (ERPF) as measured by iohexol and p-amminohippurate (PAH) clearance. Secondary endpoints are the estimation of intrarenal hemodynamic parameters derived from Gomez equations, markers of tubular injury and changes in systemic hemodynamic properties. Additionally, the M-value as a marker of insulin sensitivity will be determined using a hyperinsulinemic euglycemic clamp technique.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The burden for participants consists of three study visits, two of which will replace scheduled meetings that are a part of standard healthcare practice. In total, participants will receive one venapuncture and four intravenous cannulas, from which blood will be sampled (study total of 275L) and iohexol + p-amminohippurate will be administered to measure GFR and effective renal plasma flow respectively. After measurement of renal function, insulin sensitivity will be measured using a variable infusion of glucose and insulin (hyperinsulinemic euglycemic clamp). In addition, participants will be asked to collect two 24-hr urine samples on the days prior to the second and third study visit. During the test visits, four additional urine samples will be collected. Finally, participants will be subjected to two different non-invasive measurement techniques: finger-plethysmography (Nexfin®) and pulse-wave-analysis (SphygmoCor®). The total risk of negative effects for participants in the current study is considered low.
The transgender population is a unique population in which the effects of exogenous cross-sex hormone administration can be studied. This study may provide additional data on the safety of hormone therapy in this population and may also lead to meaningful insights regarding the physiologic effects of sex hormones on renal function in humans that may help

to understand observations from cohort studies which indicate differences in progression to end stage kidney disease (ESKD) dependent on gender.

Doel van het onderzoek

Sex differences in renal physiology is a vastly understudied area, despite known differences in sex-specific rates of chronic kidney disease. Renal function decline is accelerated in men compared to women, suggesting a potential harmful role for testosterone. Transgender individuals undergoing hormone therapy provide a unique model to study the effects of gender affirming hormone therapy on kidney function and renal physiology.

Onderzoeksopzet

13 weeks

Contactpersonen

Publiek

VUmc
Sarah van Eeghen

0645376907

Wetenschappelijk

VUmc
Sarah van Eeghen

0645376907

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Diagnosed with gender dysphoria according to DSM-V (transmen or transwomen)
- Age between 18 and 30 years

- Expected to start cross-sex hormone treatment in the upcoming month

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Current use of sex hormones
- Participation in other studies
- Concomitant use of medication (specifically: blood pressure lowering products, anti-depressants, anti-psychotic agents or medication prescribed for the treatment of attention deficit hyperactivity disorder),
- Known kidney disease (eGFR < 60 ml/min; UACR > 2,5 mg/mmol)
- Diabetes mellitus
- A history of cardiovascular disease (myocardial infarction; cardiac surgery or revascularization, unstable angina, heart failure, transient ischemic attack, cerebrovascular disease or a previously undiagnosed arrhythmia
- Known iodine related allergies

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	27-09-2021
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:	11-06-2021
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	NL9517
Ander register	METc VUMC : 2020.0674

Resultaten