Kidney FuNction in people receiving Gender affirming Hormone Therapy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23894

Source
Nationaal Trial Register

Brief title
KNIGHT-study

Health condition

Research in renal physiology

Sponsors and support

Primary sponsor: Dr. D.H. van Raalte Department of Endocrinology, VUMC/AMC De Boelelaan 1117, 1081 HV, Amsterdam E-mail: d.vanraalte@amsterdamumc.nl
Source(s) of monetary or material Support: scholarships and professional fees

Intervention

Outcome measures

Primary outcome

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 outcome

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.

Study description

Background summary

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.

Study objective

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.

Study design

13 weeks

Contacts

Public
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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-09-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-06-2021
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	NL9517
Other	METc VUMC : 2020.0674

Study results