Kidney fuNction in people receiving Gender Affirming Hormone Therapy

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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.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON52715

Source
ToetsingOnline

Brief title
KNIGHT-study

Condition

- Other condition

Synonym
kidney function, renal physiologie

Health condition

het betreft fysiologisch onderzoek

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: beurzen en honoraria

Intervention

Keyword: Hormone therapy, Kidney function, Transgender

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.

Study description

Background summary

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 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 burden and risks

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 250mL) and iohexol + p-amminohippurate will be administered to measure GFR and effective renal plasma flow respectively. In addition, participants will be asked to collect a 24-hr urine sample on the day prior to the second and third study visit. During the test visits, four additionally 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Transgender individuals starting gender affirming hormone therapy
18 years or older of age

Exclusion criteria

Iodine allergy
use of prescribed medication

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

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

Type:	Actual

Ethics review

Approved WMO Date:	22-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL74561.029.20