Abnormal sex hormone exposure of the brain; possible neuroendocrine implications for cognition in adult transsexuals and women with polycystic ovarian syndrome as clinical models

Published: 12-11-2009 Last updated: 30-11-2024

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

Summary

ID

NL-OMON36332

Source ToetsingOnline

Brief title Sex hormones and cognition

Condition

- Other condition
- Gonadotrophin and sex hormone changes

Synonym

Polycyctic ovarian syndrome, transsexuality

Health condition

Geslachtsaanpassende behandeling voor genderdysforie

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Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W,Stichting wetenschappelijk onderzoek gynaecologie (SWOG)

Intervention

Keyword: cognitive functioning, functional MRI, gender differences, sex steroids

Outcome measures

Primary outcome

- Blood oxygen level dependent (BOLD) response in functional MRI
- Test results from the neuropsychological assessments

Secondary outcome

- Reproductive endocrine serum samples
- Blood pressure
- Anthropometric measurements
- Depression score
- Anxiety score

Study description

Background summary

Clinical observations demonstrate convincingly that in men and women sex steroids exert effects on the brain. Studying these sex steroid related functions is important to better understand brain development and potential benefits of interventions and medication. However, in humans these functions have as yet hardly been studied under experimental conditions. Under normal circumstances in the human both in males and in females a combination of androgen and estrogen exposure is present. This implies that suggested specific effects of male and female sex steroids is not confined to the female sex hormone estrogen in females and the male sex hormone testosterone in males. With regard to functioning of the brain, there is evidence that estrogens exert effects in males and that androgens have effects in females. However, hardly any human studies exist that clearly distinguish estrogen only and androgen only effects on brain function either in the male or the female.

This confusion is because in males a substantial quantity of androgens are converted into estrogens by the enzyme aromatase and in females the ovaries but also the adrenals produce androgens.

With our research paradigms we can contribute to this field of sexsteroid dependant brain function in a unique way.

Study objective

The overall aim of the present work is to evaluate the individual role of androgens and estrogens on brain function in the human with a focus on cognition. Both clinical models give us the opportunity to evaluate cognitive functions and brain activity in unique conditions. By testing cognitive functions and brain activity on different time points with different sex steroid levels, we hope to understand more about the effects of sex steroids on cognitive functioning. Furthermore, we want to study several aspects of brain function when a clear imbalance between these hormones in particular in women is present due to overexposure to androgens.

Study design

Model 1: transsexuals

After diagnosis, the first phase of sex reassignment is a hormonal therapy to suppress endogenous secondary sex characteristics and to stimulate upcoming of secondary characteristics of the desired other sex. During suppression and after admiration of cross-sex steroids the subjects will be evaluated with a neuropsychological assessment and functional MRI (fMRI).

Model 2: women with PCOS

Also the women with PCOS will be examined twice. Before and after three months of anti androgen treatment the subjects will be evaluated with a neuropsychological assessment and an fMRI. The healthy control group will be examined twice without any intervention.

Study burden and risks

The subjects will not be exposed by other risks then the regular health care.

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Their treating physician will start the hormonal treatment needed. This project will add two time points to evaluate brain functions and activity with a neuropsychological assessment and an MRI. Magnetic resonance has no known risks so far.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- Gender identity disorder according DSM-IV-TR
- Polycystic ovary syndrome (PCOS) with clinical or biochemical signs of hyperandrogenism
- Eligible for hormone treatment

Exclusion criteria

- Persons with insufficient command of the Dutch language
- Unadjusted endocrine disorders
- Current treatment with sex steroids
- Neurological or psychiatric disorders that could lead to deviant test results
- Neuropharmacological intervention
- Alcohol (>5 units per day) or drug abuse
- Contra indications for an MRI scan
- Excessive androgen production other than the hypersecretion of androgens from the ovaries
- Pregnancy (excluded by a pregnancy test)
- Current desire to have children

Study design

Design

Primary purpose: Other	
Masking:	Open (masking not used)
Allocation:	Non-randomized controlled trial
Intervention model:	Other
Study type:	Observational invasive

Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	01-06-2010
Enrollment:	100
Туре:	Actual

Ethics review

Approved WMO	
Date:	12-11-2009
Application type:	First submission

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METC Amsterdam UMC
12-07-2011
Amendment
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

ID: 22065 Source: NTR Title:

In other registers

Register CCMO

ID NL29233.029.09