# **Research of possible effect of sex steriods to the brain.**

No registrations found.

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

# **Summary**

## ID

NL-OMON22065

**Source** Nationaal Trial Register

Brief title NIC-MRI

#### Health condition

Hormones, cognition, functional MRI, transsexualism, polycystic ovarian syndrome, PCOS, estrogens, androgens

## **Sponsors and support**

Primary sponsor: - Stichting wetenschappelijk onderzoek (SWOG) Contactgegevens: VU University Medical Center Department of obstetrics and gynaecology p.o. box 7057, 1007 MB Amsterdam The Netherlands Telephone: +31-20-4444444 - Neuroscience campus Amsterdam (NCA) VU University Medical Center Department of Medical Psychology p.o. box 7057, 1007 MB Amsterdam The Netherlands Telephone: +31-20-4444444 Source(s) of monetary or material Support: Hersenstichting, Nederland

Nuts-Ohra, Nederland

## Intervention

## **Outcome measures**

#### **Primary outcome**

1. Blood oxygen level dependent (BOLD) response in functional MRI;

2. Test results from the neuropsychological assessments. We will evaluate different cognitive domains with a neuropsychological test battery. The cognitive domains to be evaluated are attention, perceptual speed, memory (verbal and visual) and executive functioning (working memory, fluency and set shifting). We will also

present a task to estimate the intelligence level and questionnaires to gather information about the medical history, socio-demographic characteristics and anxiety or depression (SCL '90, HADS).

#### Secondary outcome

- 1. Reproductive endocrine serum samples;
- 2. Blood pressure;
- 3. Anthropometric measurements;
- 4. Depression score;
- 5. 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.

Objective of the study:

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 objective

The general objectives of this study is to test whether estrogens and androgens in both males and females affect cognitive functions and brain activity.

#### Study design

N/A

#### Intervention

Model 1: Transsexuals:

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# Contacts

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# **Eligibility criteria**

## **Inclusion criteria**

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

## **Exclusion criteria**

- 1. Persons with insufficient command of the Dutch language;
- 2. Unadjusted endocrine disorders;
- 3. Current treatment with sex steroids;
- 4. Neurological or psychiatric disorders that could lead to deviant test results;
- 5. Neuropharmacological intervention;
- 6. Alcohol (>5 units per day) or drug abuse;
- 7. Contra indications for an MRI scan;
- 8. Excessive androgen production other than the hypersecretion of androgens from the
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ovaries;

- 9. Pregnancy (excluded by a pregnancy test);
- 10. Current desire to have children.

# Study design

# Design

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

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2010
Enrollment:	80
Туре:	Anticipated

# **Ethics review**

Positive opinion	
Date:	02-09-2010
Application type:	First submission

# **Study registrations**

# Followed up by the following (possibly more current) registration

ID: 36332 Bron: ToetsingOnline

Titel:

# Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL2386
NTR-old	NTR2493
ССМО	NL29233.029.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36332

# **Study results**

#### Summary results

N/A