Research of possible effect of sex steriods to the brain.

Gepubliceerd: 02-09-2010 Laatst bijgewerkt: 15-05-2024

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

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

Samenvatting

ID

NL-OMON22065

Bron
Nationaal Trial Register

Verkorte titel
NIC-MRI

Aandoening

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

Ondersteuning

Primaire sponsor: - Stichting wetenschappelijk onderzoek (SWOG)
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Overige ondersteuning: Hersenstichting, Nederland
Nuts-Ohra, Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 ovaries;

9. Pregnancy (excluded by a pregnancy test);

10. Current desire to have children.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2010
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-09-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36332
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A