Androgen sensitivity in women.

No registrations found.

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

Summary

ID

NL-OMON25052

Source
Nationaal Trial Register

Health condition

Androgen sensitivity
Serotonergic sensitivity
Female sexual dysfunction
Androgeen sensitiviteit
Serotonine sensitiviteit
Seksueel disfunctioneren bij vrouwen

Sponsors and support

Primary sponsor: Emotional Brain BV Almere
Source(s) of monetary or material Support: Alan Turing Institure Almere

Intervention

Outcome measures

Primary outcome

1. [CAG]n (blood);

2. Calculated second to fourth digit ratio (handscan);

3. Pre-attentional bias for erotic stimuli (Stroop task);

4. Blood serum free testosterone levels.

Secondary outcome

1. Blood serum levels ADT-G, 3µ-diol-G, DHEA and DHEA(s);

2. Genotype SERT and 5HT1a receptor (blood);

3. Questionnaires: SAQ, SSEQ and SMQ.

Study description

Background summary

This study is a cross-sectional study to evaluate androgenicity and androgen (re)activity in women by using attention for erotic stimuli (Stroop task) as well as CAG repeat length polymorphism of the androgen receptor, free testosterone levels and 2D:4D ratio in relation to sexual functioning. Sexual functioning is examined using the validated Sexual Functioning Questionnaire (42,43), a trait questionnaire measuring 7 domains of sexual functioning (desire, arousal-sensation,arousal-lubrication, pain, orgasm, enjoyment and partner), the Sexual Anamnesis Questionnaire (SAQ), which assesses sexual functioning, as described in the DSM-IV-TR, the Sexual Motivation Questionnaire (SMQ), a trait questionnaire measuring propensity for sexual excitation and sexual inhibition, and the Sexual Satisfaction of an Event Questionnaire (SSEQ), a state questionnaire measuring sexual satisfaction of a single sexual event. As a possible biological basis for maladaptive sexual inhibitory systems, polymorphisms of SERT and 5HT1a receptor are investigated.

The entire study will be performed in the Netherlands,

Study objective

To evaluate variations of androgenicity and androgen (re) activity in (apparently) eugonadal women by using CAG repeat length polymorphism ([CAG]n) of the androgen receptor, free testosterone levels, 2D:4D ratio and attention for erotic stimuli (Stroop task) in relation to sexual functioning.

Study design

All above mentioned outcomes (primary and secondary) are measured at the same visit, considering this study consists of only one visit for the subject. Methods are mentioned above as well.

Intervention

After giving written informed consent and meeting the in- and exclusion criteria these subjects are enrolled in the study. The subjects will visit the study site once. An urine drug screening and alcohol breath test is performed, to exclude possible interference when performing the Stroop task. Also an urine pregnancy test will be performed to exclude the influence of pregnancy on the hormonal spectrum.

The visit to the study site will contain the following actions (in this order):

1. Giving written informed consent;

2. Urine drug analysis, pregnancy test and alcohol breath test;

3. Enrolment;

4. Stroop task;

5. Filling out questionnaires: SAQ, SFQ, SSEQ and SMQ;

6. Hand scan measuring the digit ratio;

7. Blood sample collected for determination of [CAG]n, genotype SERT and 5HT1a receptor and hormone spectrum.

Contacts

Public
Louis Armstrongweg 78
Saskia Poels
Almere 1311 RL
The Netherlands
+31 (0)36 5468346
Scientific
Louis Armstrongweg 78
Saskia Poels
Almere 1311 RL
The Netherlands
+31 (0)36 5468346

Eligibility criteria

Inclusion criteria

1. Provision of written informed consent;

2. Female 21-70 years of age;

3. Healthy according to normal results of medical history;

4. Subject must be heterosexually oriented;

5. BMI ≥ 18 and ≤ 30 kg/m2;

6. Dutch as first language,

Exclusion criteria

1. Subjects who have had hand surgery interfering with measurement of digit lengths;

2. Subjects with musculoskeletal conditions affecting the measurements of digit lengths;

3. Known conditions associated with abnormal prenatal androgen exposure, namely congenital adrenal hyperplasia and complete androgen insensitivity syndrome;

4. Positive drug test and/or positive alcohol test;

5. Subjects with dyslexia;

6. Subjects who are color-blind;

7. Positive urine pregnancy test;

8. Use of oral contraception containing anti-androgens (e.g. Diane 35; Minerva);

9. Use of oral contraception containing 50 µg estrogen or more;

10. Homosexual orientation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-12-2010
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-12-2010
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	NL2536
NTR-old	NTR2654

Register	ID
Other	MEC : P10-40
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A