Identification of psychometric and biological markers to assess androgen and serotonergic sensitivity in relation to sexual functioning in women.

Published: 02-12-2010
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Primary objective:To evaluate variations of androgenicity and androgen (re) activity in (apparently) eugonadal females by using CAG repeat length polymorphism ([CAG]n) of the androgen receptor, free testosterone levels, 2D:4D ratio and attention for…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual function and fertility disorders
Study type	Observational invasive

Summary

ID

NL-OMON34558

Source
ToetsingOnline

Brief title
Androgen sensitivity in women.

Condition

- Sexual function and fertility disorders

Synonym
Female Sexual Dysfunction; Hypoactive Sexual Desire Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Emotional Brain

Source(s) of monetary or material Support: Emotional Brain BV;sponsor

Intervention

Keyword: Androgen sensitivity, Female Sexual Dysfunction, Serotonergic sensitivity

Outcome measures

Primary outcome

1. [CAG]n

2. Calculated second to fourth digit ratio

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

4. Blood serum free testosterone levels

Secondary outcome

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

2. Genotype SERT and 5HT1a receptor

3. Questionnaires: SAQ, SSEQ and SMQ

Study description

Background summary

Several studies have demonstrated that for women suffering from HSDD whose low initial sensitivity to sexual cues was boosted by sublingual testosterone, the combination of testosterone and a PDE-5 inhibitor induced higher levels of vaginal blood flow when exposed to sexual stimuli, coupled with subjective reports of more intense genital sensations and sexual lust . It was also shown that neither testosterone nor a PDE-5 inhibitor produced these effects in women with HSDD when administered separately . In these same studies, subjects who did show an increased pre-attentional bias for sexual stimuli before testosterone administration, showed a decrease in pre-attentional bias after testosterone administration. Since these women showed no increase in vaginal blood flow or subjective reports of genital sensations in any of the drug conditions, and because most of them had a history of negative sexual experiences, it was hypothesized that this group suffered from maladaptive activity of sexual inhibitory systems. To further investigate this last group

the genotype of the serotonin transporter and 5HT1A receptor is measured. We hypthesize that women with one variant of the SERT/5HT1a genotype are at greater risk to develop sexual dysfunction.

Various testosterone concentrations within the normal range more or less saturate androgen receptors. Thus, it can be argued that within the range of normal hypothalamic-pituitary-gonadal (HPG) -axis function and eugonadal plasma testosterone concentration, genetically determined functional difference in androgen receptor activity in target tissues can be observed and will be of clinical significance.
The influence of testosterone on sensitivity of the brain might be mediated by different possibly interrelated variables. A first possible intervening variable is associated with the androgen receptor. Variations in CAG repeat length polymorphism ([CAG]n)of the androgen receptor gene causes variation in the influence of testosteron on androgen sensitivity. We assume that women with a relative long [CAG]n and low serum free testosterone might have a relative less functioning androgen system, and consequently a relative insensitive system for sex. A second possible intervening variable is related to the differentiation between organizational and activational effects of testosterone on the brain. 2D:4D digit ratio is suggested to be a retrospective marker of prenatal testosterone exposure. We assume that women with a relative long [CAG]n have higher 2D:4D ratios than women with a relative short [CAG]n.

Study objective

Primary objective:
To evaluate variations of androgenicity and androgen (re) activity in (apparently) eugonadal females 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).

Secondary objectives:
- To validate questionnaires involving subjective rating of sexual satisfaction and sexual functioning.
- To investigate a possible biological basis for maladaptive sexual inhibitory systems by genotyping the polymorphisms in the Serotonin Transporter (SERT) and 5HT1a receptor.
- To explore possible correlations between blood serum levels ADT-G, 3α-diol-G, DHEA and DHEA(s) and [CAG]n/2D:4D ratio.

Study design

This is a cross-sectional study with a total of two hundred subjects visiting the study site once. During this visit subjects perform a Stroop task and fill out questionnaires partly based on a retrospective sexual event. A hand scan will be made and at the end of the visit a blood sample will be drawn.

Study burden and risks

There are no risks associated with participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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 invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	02-12-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	04-01-2011
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL34244.044.10