Sexual response in women affected with diabetes mellitus type 1: A controlled laboratory study measuring genital and self-reported sexual arousal

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The present study will investigate vaginal blood flow, measured by vaginal photoplethysmography, in pre- and post-menopausal women affected with DM type 1, and in an age and menopausal status matched sexually functional control group. Changes in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON32504

Source
ToetsingOnline

Brief title
Sexual response in women affected with diabetes mellitus type 1

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Gonadotrophin and sex hormone changes

Synonym
diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diabetes mellitus, Female sexual function, Sexual arousal, Vaginal photoplethysmography

Outcome measures

Primary outcome

Outcome of vaginal photoplethysmography en subjective sexual arousal

measurement.

Secondary outcome

report of sexual problems

Study description

Background summary

Erectile dysfunction is a well-established complication of diabetes mellitus (DM), with the prevalence increasing with age[1]. The sexual function of women with DM has received much less attention in clinical research. However, recent controlled prevalence studies indicate that DM increases the risk of female sexual dysfunction, primarily sexual arousal and lubrication problems[2-4]. The pathophysiology of DM-associated sexual dysfunction in men is known to include endothelial and smooth-muscle dysfunction and autonomic neuropathy[1]. In women, micro vascular and neuropathic complications may also play a role in sexual dysfunction. In view of the evidence for decreased sexual arousal and lubrication in women with DM, research applying objective physiological measures of sexual response in this population seems highly useful. To date, only few studies included such measures. One very small study measured vaginal blood flow by vaginal photoplethysmography and observed reduced vaginal blood flow in diabetic women[5]. Other studies observed reduced baseline clitoral blood flow in women affected with DM [6], and decreased genital vibration sense [7]. Taken together these studies indicate diminished genital vascular responsiveness and genital tactile sensitivity in women with DM. However, to

establish and extend research findings further research is necessary.

Study objective

The present study will investigate vaginal blood flow, measured by vaginal photoplethysmography, in pre- and post-menopausal women affected with DM type 1, and in an age and menopausal status matched sexually functional control group. Changes in vaginal blood flow and subjective sexual arousal in response to visual erotic and clitoral vibrotactile stimulation will be measured. Also the association between DM complications and sexual responsiveness will be investigated.

Study design

All women will visit the hospital one time. During this visit they will fill in questionnaires about socio-demographic variables, sexuality and psychological functioning and for women older than 40 this it will include a venous blood sample. For diabetic women the visit will include also a limited neuro-vascular assessment and determination of HBAC level. All participants will go through a 1-hour experimental session with vaginal photoplethysmography. For diabetic women, data on duration of disease and vascular complications will be retrieved form the medical records.

Study burden and risks

After they have given written acknowledgement of informed consent to participate, a medical and psychiatric screening will take place. The participants will receive a financial compensation for their participation in the study; diabetic women will receive ¤65,-, and control women will receive ¤45,-. A proportional payment will be made when the volunteer leaves on her own wish before study completion, or when, based on the screening, the participant is asked by the investigators to discontinue the study for medical or psychiatric reasons. The amount of the financial compensation is based on the standard compensations that are generally accepted in this field of research. Travel expenses will be compensated with a maximum of ¤45,-.
The vaginal photoplethysmograph used in this study is considered a safe device. No harmful events have been reported. Furthermore, the device used to measure genital arousal and the vibrator will be sterilized before each use, according to plasma sterilization procedure. From previous studies in our laboratory it is known that the genital vibrotactile stimulation will not cause harm or discomfort.

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) are >= 18 < 70 years old, 2) have DM type 1, 3) have a heterosexual orientation

Exclusion criteria

homosexual orientation (because of the heterosexual erotic stimuli), pregnancy or lactation, a diagnosis of affective, psychotic or substance related disorder according to DSM-IV-TR, having undergone a hysterectomy or prolapse surgery, current use or recent use (less than 4 weeks before participation) of medication that may affect sexual response, disorders of the genitals that may influence the sexual response or the measurement of the response, and other medical disorders than DM that may influence the sexual response or the measurement of the response

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2010
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	02-02-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL30753.058.09