Sexual functioning in women with the Mayer-Rokitansky-Küster-Hauser syndrome (MRKH syndrome) and their partners and physiological sexual arousal responses in these women with a surgical or non-surgical created neovagina

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The study comprises 2 parts.Part 1: Primary: to assess sexual functioning, sexual self image and psychological and relational functioning in MRKH women with surgical or non- surgical created neovaginas and their partners and make a comparison with...

Ethical review	Approved WMO
Status	Suspended
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON44138

Source
ToetsingOnline

Brief title
Sexual and physiological functioning of MRKH women and their partners

Condition

- Other condition
- Reproductive tract and breast disorders congenital

Synonym

Mayer-Rokitansku-Kuster-Hauser syndrome, Mullerian agenesis syndrome

Health condition

seksuele (dis)functie(s)

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: MRKH syndrome, sexual arousal response, sexual functioning

Outcome measures

Primary outcome

Part 1

Sexual functioning within a heterosexual relationship, measured with validated questionnaires (* * Female sexual function index (FSFI), Female sexual distress scale (FSDS), ; **International Index of erectile function (IIEF), Male sexual distress scale (MSDS)).

Part 2

Genital sexual arousal, measured with vaginal photoplethysmography that assesses changes in vaginal pulse amplitude (VPA), reflecting the phasic changes in vaginal engorgement during an experimental session; subjective sexual arousal measured through self-reported ratings of sexual arousal collected after the neutral and the erotic stimuli;

Secondary outcome

Part 1:

Sexual self image measured with the Rosenberg*s Self Esteem Scale (RSES),

Sexual Esteem Scale (SES) and Female Genital Self-image Scale (FGSIS) (only for

* *) .

Psychological functioning assessed with the Symptom Checklist (SCL)-90 and

Hospital Anxiety and Depression Scale (HADS) (for * * and **).

Relational functioning by assessment of relationship satisfaction using the

Maudsley Marital Questionniare (MMQ) (for * * and **).

Evaluation of an association between sexual functioning of MRKH women and these

secundary outcome variables

Part 2:

Evaluation of a possible association between the kind of treatment (surigal

versus non surgical) and changes in vaginal blood flow; an association between

the kind of surgery and vaginal blood flow responses will be examined

exploratorily.

Study description

Background summary

Surgical as well as non- surgical treatment is offered to create a neovagina in women affected with the Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome (uterus and vagina agenesis). Assessment of sexual functioning after treatment yields conflicting results. It can be questioned whether sexual functioning of these women is affected by hampered sexual self image, by impaired psychological or relational functioning, by partners' sexual dysfunction or by a reduced sexual

response of their neovaginas from a physiological point of view.

Study objective

The study comprises 2 parts.

Part 1: Primary: to assess sexual functioning, sexual self image and psychological and relational functioning in MRKH women with surgical or non-surgical created neovaginas and their partners and make a comparison with the results of age-matched women without the condition and their partners. Secondary: to evaluate an association between sexual functioning and sexual self image, psychological and relational functioning

Part 2: Primary: to investigate genital arousal using vaginal photoplethysmography and subjective sexual arousal in pre-menopausal MRKH women compared with age-matched women without the condition when confronted with neutral and erotic film exerpts. Secondary: to evaluate differences in genital and subjective sexual arousal responses between the surgically and non-surgically reconstructed neovaginas and to explore an association between vaginal blood flow responses and the kind of surgery that was performed to create a neovagina

Study design

case control study

Study burden and risks

Part 1: All eligible MRKH women, age-matched control women and their partners, who have consented for study participation complete a set of questionnaires about socio-demographic variables, sexual functioning, sexual self image, psychological and relational functioning via a personal portal on a licensed version of Netquestionnaires 6.0 or are provided with the paper and pencil version of the questionnaires.

Part 2: All female participants, MRKH and control women, will visit the hospital (LUMC) one time and go through a 1-hour experimental session with vaginal photoplethysmography. Before the start all women will undergo a gynaecological examination to assess length of their (neo)-vagina.

Vaginal photoplethysmography does not cause harm or discomfort. Self-insertion of the plethysmograph (with the size of a menstruation tampon) and completion of questionnaires about sexual functioning and sexual self image may be experienced as uncomfortable

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

All participants must have a sexual relation with a male partner for at least six months. Furthermore,
Part 1, questionnaire study: All MRKH women with a neovagina, surgically as well as non surgically created, are invited. Control women are healthy females without the condition, age-matched with the study population. Via these women their partners are asked to participate.
Part 2: psychophysiological assessment:
Those MRKH as well as control women, participants of part 1 of the study, and aged between 18-45 years old.

Exclusion criteria

For part 1 & 2:
unable to speak, understand and write the Dutch language
pregnancy or lactation (control women only);Only for part 2
* the depth of the neovagina is too small to carry the probe for the photoplethysmographic device (MRKH women only)
* having a disease that is known to affect genital response (such as Diabetes Mellitus, Multiple Sclerosis, Radical hysterectomy).
* current use or recent use (less than 4 weeks before participation) of medication that may affect genital responses.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-09-2015
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	26-05-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO Date:	17-10-2016
Application type:	Amendment
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	NL52000.058.15