Reinnervation of the clitoris and/or vaginal surface in patients with a low spinal lesion or spina bifida: the TOMAX-procedure for Women

Published: 30-08-2016
Last updated: 15-04-2024

Reinnervation of the clitoris in patients with a low spinal lesion (Th12-L1) by nerve-transposition of the ilio-inguinal nerve towards the dorsal clotiridis nerve. By restoring the genital sensation in women with low spine lesion can increase the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55659

Source
ToetsingOnline

Brief title
TOMAX-procedure for Women

Condition

- Other condition
- Spinal cord and nerve root disorders
- Sexual dysfunctions, disturbances and gender identity disorders

Synonym
Absence of genital sensation due to lower spinal lesion or spina bifida

Health condition

gewaarwording van urine-continentie

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Niet van toepassing.

Intervention

Keyword: clitoris, genital sensation, nerve transposition, spina bifida, spinal lesion, vagina

Outcome measures

Primary outcome

Patients will be evaluated pre-operatively and four times postoperatively (at

2weeks, 6,12 and 18 months):

- Neurological sensory tests for touch and temperature stimuli

- Quantitative fine-touch sensitivity will be determined using Semmes-Weinstein

monofilaments

Secondary outcome

Psychological functioning and sexuality will be evaluated pre-operatively and

once postoperatively (at 18 months) by using:

- the Hospital Depression and Anxiety Scale (HADS) questionnaire to determine

the patients* level of distress

- the Symptom Check list-90-R (SCL90-R) to measure psychoneuroticism.

- the Groninger Arousability Scale (GAS)16 to assess the patients ability to

experience the stages of the sexual response cycle.

- FSDS-R *proxy*measure voor sexual distress

- FSFI a questionnary for sexually active women

- SESII-W an inhibition / excitation questionnary

These tests will be measured by a clinical psychologist trained in sexuology

Study description

Background summary

Background:
Almost all female patient with spina bifida have complete absence of sensibility of the clitoris and vagina. The same thing is reported for women with lower spinal injuries (dysfunction and sexual dysfunctie, do lead a normal life. The psychosexual frustration in this female population is high. They can have sexual interaction, but have complete absence of sensibility in the vagina and clitoris.

Dr. M.L.E. Overgoor recently doctorated on the reinnervation of sensibility of the penis with male lower spinal injuries or spina bifida by performing the so called TOMAX-procedure. This involves micro-surgically connecting the sensory ilioinguinal nerve (L1) to the dorsal nerve of the penis unilaterally. Tactile- and erogenous-like sensibility was restored in the glans penis in patients with a low spinal lesion. This new sensation enhanced the quality of sexual functioning and satisfaction. Restoring genital sensation in women with low spinal lesion can increase the quality of women*s sex lifes as well.
As a side effect a better control of urinary incontinency and awareness has been reached in several patients.

The good results of this procedure with males has increased the interest of female patients with lower cord injuries or spina bifida to perform a similar procedure to reinnervate the clitoris and/or vagina. It is to be expected that this procedure will enhance the quality of life, sexual functioning and satisfaction.

Study objective

Reinnervation of the clitoris in patients with a low spinal lesion (Th12-L1) by nerve-transposition of the ilio-inguinal nerve towards the dorsal clotiridis nerve. By restoring the genital sensation in women with low spine lesion can increase the quality of life, sexual functioning and satisfaction
As a side effect a improved awareness of urine incontinency can be expected.

Study design

A prospective trial, with an therapeutical intervention to reinnervate the clitoris. There will not be a control group.

Intervention

Nerve transposition (ilioinguinal nerve to the dorsal nerve of the clitoris / pudendal nerve) during an operation under local anesthesia (spinal block) or general anesthesia.

Study burden and risks

Pre-operative:
- visit to out-patient clinic for physical examination and selection
- psychological test by sexuologist

Patients will be evaluatie at least 3 times postoperative:
1. Postoperative examination of the wound 2 weeks postoperative
2. out patient clinic visit for physical examination by the plastic surgeon 6 months postoperative
3. out patient clinic visit for physical examination by the plastic surgeon 12 months postoperative
4. out patient clinic visit for physical examination by the plastic surgeon 18 months postoperative and psychological tests by sexuologist.

- General complications following an operation:
- Loss of sensibility of the groin
- failure of the procedure which leads to the pre-operative condition of absence of sensibility of the clitoris.

Contacts

Public
Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025 AB
NL
Scientific
Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

-Women with a (traumatic) low spinal lesion or spina bifida below L1 who have no sensation in the clitoris and vaginal surface but with normal groin sensation.

Exclusion criteria

- Spinal lesion above L1 and
- diminished or absent groin sensation
- negative sexual experiences
- psychologically unstable (estimated by our sexologist on the basis of HADS/SCL-90 questionaries)
-intact clitoral/vaginal wall sensation

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-01-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	30-08-2016
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	30-08-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-02-2022
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	07-02-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL46780.075.15