Sexual function following the MiniArc procedure

Published: 09-06-2009
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Objective: To determine the effect of a MiniArc procedure on female sexual function in relation to the surgical procedure and it's treatment result. Also to evaluate the determinants of this effect.

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

Summary

ID

NL-OMON33286

Source
ToetsingOnline

Brief title
sexual function following Miniarc

Condition

- Other condition

Synonym
sexual function

Health condition

seksuele functie

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: uit afdelingsbudget

Intervention

Keyword: female sexual dysfunction, MiniArc, sexual function, stress urinary incontinence

Outcome measures

Primary outcome

A. To determine the effect of a MiniArc procedure on female sexual function in

relation to the surgical procedure and it's treatment result.

B. Also to evaluate the determinants/causal factors of this effect.

Secondary outcome

Parameters/outcome:

• anwsers to the general questions

• the (subjective) treatment result

• total score FSFI preoperatively compared to postoperatively

• subscores of the GRISS preoperatively compared to postoperatively

• subscores of the GRISS of the partner preoperatively compared to

postoperatively

• anwsers to the questions about sexuality by the partners preoperatively

compared to postoperatively

Study description

Background summary

Background: Surgical treatment of stress urinary incontinence may have a

positive or negative effect on female sexual function. The MiniArc procedure is a relatively new procedure and has a 'single incision approach' which is minimal invasive.
The effect of the MiniArc procedure on female sexual function has not yet been evaluated.

Study objective

Objective: To determine the effect of a MiniArc procedure on female sexual function in relation to the surgical procedure and it's treatment result. Also to evaluate the determinants of this effect.

Study design

Methods: Prospective multicentre questionnaire study.
Materials: Questionnaires. First general questions, then the validated Female Sexual Function Index, the Female Sexual Distress Scale and the Golombok Rust Inventory of Sexual Satisfaction. Also a questionnaire for the partner of the patient (Golombok Rust Inventory of Sexual Satisfaction for men).

Study burden and risks

Not burden or risks.

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

- female patients who will undergo the MiniArc procedure for stress urinary incontinence
- >18 years old
- in a relationship with a partner

Exclusion criteria

- medical histery of vaginal surgery
- <18 years old
- patients who do not speak Dutch

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2009
Enrollment:	100

Type:	Actual

Ethics review

Approved WMO Date:	09-06-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	17-06-2009
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	NL26877.058.09