1-year results after MiniArc.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26940

Source
Nationaal Trial Register

Health condition

(stress) urinary incontinence, miniarc, single incision sling.

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: fund=initiator

Intervention

Outcome measures

Primary outcome

Percentage females without stress urinary incontinence.

Secondary outcome

Percentage females with urge urinary incontinence after surgery.

Study description

Background summary

N/A

Study objective

The aim of this study is to evaluate the succesrate of the MiniArc.

Study design

All patients were asked to fill in a urinary chart (bijlage) for two days, listing the frequency and amount of intake and peeing. They were also asked to state if, when and how severe they suffer from urinary (stress) incontinence. Patients were familiar with the procedure.

Patients were seen by two doctors (LLN, FvM) familiar with the complaints and symptoms of incontinence. All patients underwent a PAD test and a coughing stress test.

For the PAD test patients were asked to walk, talk, laugh, cough etc for one hour wearing a provided pad without going to the toilet to pee. After one hour the PAD was weighted. With a full bladder patients were asked to take place in the gynaecological chair. With a bladders scan the volume was measured. Patients were then asked to cough 3 times and blow on their hand to see if urine leaking could be objected/observed.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

All patients (informed consent) who underwent MiniArc procedure as a treatment of stress urinary incontinence from March 2008 till January 2011 in the Flevohospital, Almere.

Exclusion criteria

Not willing to participate, severe other disease in uro-gynaecological area.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-03-2012
Enrollment:	95
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-03-2012
Application type:	First submission

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
NTR-new	NL3187
NTR-old	NTR3338
CCMO	NL36271.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A