MiniMo-trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29267

Source
Nationaal Trial Register

Brief title
MiniMo.

Health condition

Stress urinary incontinence
Mid-urethral sling
MiniArc
Monarc
Post-operative pain
Cost-effectiveness

Sponsors and support

Primary sponsor: Academic Medical Center
Meibergdreef 9
1105 AZ Amsterdam
The Netherlands
Source(s) of monetary or material Support: American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343
USA

Intervention

Outcome measures

Primary outcome

1. Efficacy as surgical correction of stress urinary incontinence;

2. Post-operative pain.

Secondary outcome

1. Complications;

2. Morbidity and post-operative recovery;

3. The need for repeated stress-incontinence surgery or specialized physiotherapy;

4. Pelvic floor function;

5. Cost-effectiveness from a societal perspective.

Study description

Background summary

Background of the study:

Stress urinary incontinence (SUI) is a worldwide common problem, especially suffering women. In the past many operative techniques are developed to treat stress urinary incontinence. One of the most successful techniques is the TVT-procedure (tension free vaginal tape). Since its introduction, more than 1,000,000 procedures with TVT have been performed worldwide. A recent Cochrane review concluded that the cure rates after TVT placement were similar to those after open abdominal retropubic suspension with a low complication rate. Initially suburethral tapes followed a retropubic route during insertion. Later, the trans-obturator route was developed. One of the most used transobturator slings is the Monarc. It has been shown that the trans-obturator route is associated with a lower risk on post-operative bladder retention and overactive bladder symptoms. Furthermore, the trans-obturator route is safer as, during this procedure, it is almost impossible to perforate the bladder. However, trans-obturator slings also carry some risk on morbidity of which muscle pain (due to perforation of the obturator muscles) and bleeding (due to perforation of the obturator vessels) are the most important. With the intention to reduce the invasiveness of the retropubic and trans-obturator approach, the MiniArc was developed.

Objective of the study:

To randomly compare MiniArc and Monarc for: ƒ{ efficacy as surgical correction of stress-incontinence ƒ{ post-operative pain ƒ{ complications ƒ{ morbidity and post-operative recovery ƒ{ the need for repeated stress-incontinence surgery or specialized physiotherapy ƒ{ pelvic floor function ƒ{ cost-effectiveness from a societal perspective

Study design:

Prospective multi-national randomised controlled trial (the Netherlands, Belgium, France).

Study population:

Patients who are planned to undergo surgical correction of symptomatic stress-incontinence.

Intervention:

Surgical correction of symptomatic stress-incontinence with mini-sling (MiniArc) or trans-obturator sling (Monarc).

Primary study parameters/outcome of the study:

1. Efficacy as surgical correction of stress urinary incontinence;

2. Post-operative pain.

Secundary study parameters/outcome of the study:

1. Complications;

2. Morbidity and post-operative recovery;

3. The need for repeated stress-incontinence surgery or specialized physiotherapy;

4. Pelvic floor function;

5. Cost-effectiveness from a societal perspective.

Study objective

If MiniArc® would prove to be equally efficient as a Monarc® transobturator subfascial hammock and it would also be less morbid (including post-operative pain), the MiniArc could be the most cost-effective strategy to deal with SUI that is available at the moment.

Study design

Before operation, 4 weeks and 12/18/24/36 months after operation, patients are asked to fill in a validated questionnaire concerning pelvic floor problems and general functioning. Also they have to complete a diary during the first 4 weeks after operation, concerning pain, use of analgetics and activities of daily life. 6 Months after operation an interview by telephone will take place to complete a short questionnaire. Physical examination including a cough stress test will take place before operation, 4 weeks and 12/18/24/36 months after operation.

Intervention

Surgical correction of symptomatic stress-incontinence with single-incision sling (MiniArc) or trans-obturator sling (Monarc).

Contacts

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Eligibility criteria

Inclusion criteria

Female symptomatic stress urinary incontinence resulting from urethral hypermobility and/or ISD (intrinsic sphincter deficiency).

Exclusion criteria

1. Subjects who have stage 2 or more genital prolaps, according to the ICS-classification;

2. Subjects who undergo surgery for recurrence of stress incontinence;

3. Subjects who undergo concomitant surgical procedures;

4. Subjects who are pregnant or want to become pregnant;

5. Subjects are not capable of giving informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2010
Enrollment:	192
Type:	Actual

Ethics review

Positive opinion
Date: 06-01-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33417
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3617
NTR-old	NTR3783
CCMO	NL28973.018.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33417

Study results

Summary results
N/A