A prospective multi-national randomized comparison of the effectiveness and safety of MiniArc and Monarc.

Published: 26-11-2009
Last updated: 15-05-2024

To randomly compare MiniArc and Monarc for:* efficacy as surgical correction of stress-incontinence* post-operative pain* complications* morbidity and post-operative recovery* the need for repeated stress-incontinence surgery or specialized...

Ethical review	Approved WMO
Status	Pending
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON33417

Source
ToetsingOnline

Brief title
MiniMo-trial.

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
stress urinary incontinence, unintended urine loss.

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,American Medical Systems, Inc., Minnetonka, USA,American Medical Systems;Inc.;Minnetonka;USA

Intervention

Keyword: Cost-effectiveness, MiniArc, Post-operative pain, Stress urinary incontinence

Outcome measures

Primary outcome

1. efficacy as surgical correction of stress urinary incontinence.

2. post-operative pain.

Secondary outcome

3. complications.

4. morbidity and post-operative recovery.

5. the need for repeated stress-incontinence surgery or specialized

physiotherapy.

6. pelvic floor function.

7. cost-effectiveness from a societal perspective.

Study description

Background summary

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.

Study objective

To randomly compare MiniArc and Monarc for:

* efficacy as surgical correction of stress-incontinence
* post-operative pain
* complications
* morbidity and post-operative recovery
* the need for repeated stress-incontinence surgery or specialized physiotherapy
* pelvic floor function
* cost-effectiveness from a societal perspective

Study design

Prospective multi-national randomised controlled trial.

Intervention

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

Study burden and risks

Burden: Before operation, 4 weeks and 12 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 (15 min). All questionnaires together takes approximatively 2 hours spread over 12 months.
Risk: Both operative techniques (MiniArc and Monarc) are well accepted procedures to treat stress urinary incontinence in women. In many centres these procedures are commonly used. Therefore no extra risks are connected with inclusion in the trial.

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 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29267
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL28973.018.09
OMON	NL-OMON29267