A multi-centre randomised comparison of the effectiveness and safety of TVT-O and TVT-S.

Published: 03-01-2007
Last updated: 10-05-2024

1. To compare the effectivity of TVT-O and TVT-S as surgical correction of stress-incontinence. 2. To compare the complications of TVT-O and TVT-S.3. To compare the morbidity and post-operative recovery of TVT-O and TVT-S. 4. To compare the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Urethral disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON30427

Source
ToetsingOnline

Brief title
TVt-O versus TVT-S

Condition

- Urethral disorders (excl calculi)
- Obstetric and gynaecological therapeutic procedures

Synonym
stress incontinence (involunatary leakage of urine during exercise)

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: minimal invasive surgery, morbidity, randomized trial, stress incontinence

Outcome measures

Primary outcome

Disease specific quality of life.

Secondary outcome

1. Morbidity

2. POP-Q score (Anatomical effect)

3. General quality of life

4. Duration of catheter use

5. Performed surgical procedures in the first year after primary cystocele

repair.

Study description

Background summary

TVT has become the standard surgical procedure to correct stress-incontinence. During TVT a polypropylene mesh is, by vaginal approach, placed below the mid-urethra. Several variations of the TVT have been developed to improve the procedure and make it safer. One of these variations is TVT-O during which the mesh, that is placed below the mid-urethra, leaves the body through the groins. The mesh crosses at its path several muscles and vessels. This implies that there is a risk on muscle pain and bleeding.
To reduce the risk on muscle pain and bleeding a new variation of TVT has been developed. This variation is called TVT-S. During TVT-S the mesh that is placed below the mid-urethra does not cross muscles or vessels. The path of the mesh is shorter during TVT-S than during TVT-O as it is vaginally inserted and does not leave the body through the groins.
In this trial the effectiveness, safety and post-operative pain of TVT-O and TVT-S are randomly compared.

Study objective

1. To compare the effectivity of TVT-O and TVT-S as surgical correction of stress-incontinence.
2. To compare the complications of TVT-O and TVT-S.
3. To compare the morbidity and post-operative recovery of TVT-O and TVT-S.
4. To compare the effectivity of TVT-S performed under [1] local analgesia in combination with sedation and [2] general anesthesia or spinal analgesia.
5. To compare the need for repeated stress-incontinence surgery or specialized physiotherapy following both techniques.
6. To compare pelvic floor function following TVT-O and TVT-S.

Study design

A randomized multi-centre controlled trial will be performed

Intervention

TVT-O or TVT-S.

Study burden and risks

All patients are asked to complete a questionnaire before and at 6 weeks, 3 months and 12 months after surgery. Patients hold a diary from the day of surgery until 6 weeks after surgery. Patients visit the hospital for additional visits at 3 months and 12 months after surgery.

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

patients undergoing surgical correction of stress-incontinence

Exclusion criteria

-recurrent stress-incontinence
- genital prolapse requiring surgical intervention
- patients requiring additional surgical procedures

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):	01-01-2007
Enrollment:	150

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

No registrations found.

In other registers

Register	ID
CCMO	NL14961.018.06