

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

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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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Urethral disorders (excl calculi)
<b>Study type</b>	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 (involuntary 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

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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**

### **Public**

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### **Scientific**

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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**

CCMO

**ID**

NL14961.018.06