

# Comparison between the two transobturator inside-out procedures for the surgical treatment of female stress urinary incontinence: A randomised clinical trial

<b>Submission date</b> 07/02/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/03/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/10/2011	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
2010/EC/23, EC 2003/23

## Study information

**Scientific Title**

Clinical comparison between the original TVT-O and a modified procedure (mini TVT-O) for the surgical treatment of female stress urinary incontinence: A randomised clinical trial with 1-year follow-up

**Acronym**

TVT-O versus mini TVT-O

**Study objectives**

A shorter transobturator tape placed inside-out with minimized dissection would result in similar cure rates as those obtained with the original inside-out transobturator procedure, but may result in less post-operative pain and complications.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The Ethics Committee of University Hospital of Liege (Comité d'Ethique Hospitalo-Universitaire de Liège) approved on the 10th of October 2006 (ref: amendment #3 to EC approval # 2003/23)

**Study design**

Randomised two arm single blind controlled parallel group trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Female stress urinary incontinence

**Interventions**

Surgical treatment: original inside-out transobturator tape (TVT-O™) versus a modification of the procedure, with no perforation of the obturator membrane and a shorter tape length. The procedure lasts approx 15 minutes.

The total duration of follow up is 12 months

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. Objective and subjective cure of stress urinary incontinence at 1 year, measured by
  - 1.1. Cough test (objective cure)
  - 1.2. Measurement of Urinary Handicap (MUH), a validated self-administered questionnaire
2. Complication rates during a 1-year follow-up period, assessed by clinical examination and patient reporting at visits

## **Key secondary outcome(s)**

Incidence and severity of postoperative pain at baseline, 1 day, 1, 6 and 12 months, measured by Visual Analogue Score (VAS) - inner thigh pain assessed for each side, left and right

## **Completion date**

31/12/2008

## **Eligibility**

### **Key inclusion criteria**

1. Age between 25 and 85 years
2. Clinical and urodynamic diagnoses of Stress Urinary Incontinence (SUI)
3. Positive stress test
4. Maximum cystometric capacity 300 ml or greater

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Other

### **Sex**

Female

### **Key exclusion criteria**

1. Urodynamically proven detrusor overactivity
2. Impaired bladder contractility
3. Post void residual (PVR) 100 ml or greater
4. Contraindication to anaesthesia
5. Pregnancy
6. Neurogenic bladder
7. Active urinary or vaginal infection
8. Concomitant symptomatic and/or significant (more than second degree) pelvic organ prolapse (POP)
9. Patient not willing or unable to participate in the trial

### **Date of first enrolment**

01/01/2007

### **Date of final enrolment**

31/12/2008

## **Locations**

### **Countries of recruitment**

Belgium

**Study participating centre**  
**Service d'Urologie**  
LIEGE  
Belgium  
B-4000

## **Sponsor information**

### **Organisation**

University Hospital of Sart Tilman (CHU de Sart Tilman) (Belgium)

### **ROR**

<https://ror.org/044s61914>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

University Hospital of Liège (Belgium)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration