

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

Submission date 07/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/03/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/10/2011	Condition category 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below, to request a patient information sheet.

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2007

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

Age group

Other

Sex

Female

Target number of participants

168 (84 patients per arm)

Key exclusion criteria

1. Uroynamically 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)

Sponsor details

Urology Department

Avenue de l'hôpital 1

Bloc Central

Batiment B35

CHU Sart Tilman

LIEGE

Belgium

4000

Sponsor type

Hospital/treatment centre

Website

<http://www.chuliege.be/sm/71.html>

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital of Liège (Belgium)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration