ISRCTN65635093 https://doi.org/10.1186/ISRCTN65635093

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/03/2010	**Overall study status** Completed	
Last Edited 04/10/2011	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof David Waltregny

Contact details
Service d'Urologie
Bloc Central
Batiment B35 -1
Centre Hospitalier Universitaire (CHU) de Sart Tilman
LIEGE
Belgium
B-4000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2010/EC/23, EC 2003/23

Study information

Scientific Title
Clincial 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. 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)

Sponsor details
Urology Department
Avenue de l'hopital 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