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Randomised trial of tension-free vaginal tape and transobturator tape as treatment for urinary stress incontinence in women

Submission date	Recruitment status	[_] Prospectively registered
16/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/11/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/09/2013	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9452

Study information

Scientific Title

Study objectives
To compare the cure rate and complication rate of the tension-free vaginal tape (TVT) and tension free vaginal tape obturator (TVT-O) procedure (TVT & TVT-O, Gynecare, Somerville, New Jersey)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Urodynamic stress incontinence

Interventions
TVT versus TVT-O

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Objective cure rate (24 hour pad test)
2. Subjective cure rate (Leakage on 3 day voiding dairy)

Secondary outcome measures
1. Change in quality of life (Kings Health Questionnaire [KHQ])
2. Change in symptom severity (Bristol Female Lower Urinary Tract Symptom Questionnaire [BFLUTS], International Consultation on Incontinence questionnaire [ICIQ])
3. Pre and postoperative complications
4. Pain at 1 hour and 1 week (Visual Analogue Scale [VAS])

Overall study start date
01/10/2004

Completion date
01/10/2006

Eligibility

Key inclusion criteria
1. Urodynamic stress incontinence
2. Primary continence procedure

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Detrusor overactivity
2. Voiding Dysfunction
3. Prolapse ≥ pelvic organ prolapse quantification system (POP-Q) stage 2

Date of first enrolment
01/10/2004

Date of final enrolment
01/10/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Directorate of Women's, Perinatal & Sexual Health
Leicester
United Kingdom
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Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
Research & Development Directorate
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
University Hospitals of Leicester NHS Trust (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2011		Yes	No