

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

Submission date
16/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
11/11/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
13/09/2013

Condition category
Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Christopher Mayne

Contact details

Directorate of Women's, Perinatal & Sexual Health
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW
christopher.mayne@uhl-tr.nhs.uk

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 diary)

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 \geq 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
LE5 4PW

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

Sponsor details

Research & Development Directorate
Leicester General Hospital
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW
nicola.turner@uhl-tr.nhs.uk

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