

A randomised trial of transvaginal tape (TVT) versus transvaginal obturator tape (TVTO): a pilot study

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| Submission date 09/08/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 21/10/2010 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 06/12/2019 | Condition category Urological and Genital Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Alison Sambrook

Contact details
Department of Obstetrics & Gynaecology
Aberdeen Royal Infirmary
Aberdeen
United Kingdom
AB25 2ZN

Additional identifiers

Protocol serial number
04/0091

Study information

Scientific Title
A randomised controlled pilot study comparing transvaginal obturator tape (TVTO) to transvaginal tape (TVT) for the treatment of genuine stress incontinence in women

Study objectives

To compare the effectiveness and costs of transvaginal tape (TVT) with transvaginal obturator tape (TVTO) and to use the data on health related quality of life as measured over the trial follow-up. This pilot study aimed to recruit 20 women to each treatment arm in order to enable a power calculation to be performed to establish the number of participants required for a definitive randomised controlled trial between the experimental and control treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Grampian Research Ethics Committee, 28/05/2004, ref: 04/0091

Study design

Pilot single centre un-blinded randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stress urinary incontinence

Interventions

This is a pilot single centre un-blinded randomised controlled trial with a 12 month follow-up. Randomisation is independently prepared numbered opaque sealed envelopes stored independently from the trial office.

Patients will be randomised to one of the following:

1. Experimental treatment: transvaginal obturator tape (TVTO)
2. Control treatment: transvaginal tape (TVT)

Patients were consented on admission to hospital but had previously received verbal information and written information leaflet at the urodynamic clinic or via post and again on admission to the ward. Women were randomised to one of the two procedures once consent had been obtained. The two interventions were performed as described by the manufacturing company, Gynecare. The operating surgeons were experienced in both forms of surgery and the procedure was performed in an operating theatre under either spinal or general anaesthetic dependant on the patient choice. Women were discharged typically on the day of surgery but discharge was determined by the ability to void a normal amount of urine.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Changes in International Consultation on Incontinence Questionnaire (ICIQ), assessed at baseline
2. Differences in quality adjusted life years (QALYs) estimated from responses to the EQ-5D, measured at baseline and 12 months

Key secondary outcome(s)

1. Subjective cure rate
2. Changes in the King's Health questionnaire (KHQ) scores
3. Difference in EQ-5D scores at three and twelve months follow-up
4. Operative data
5. Self-reported acceptability
6. Usage recommendation to a friend

All measured at baseline, two weeks (except for the EQ-5D), three months and twelve months.

Completion date

31/01/2006

Eligibility

Key inclusion criteria

1. Women aged over 18 years
2. Urodynamic stress incontinence
3. Failed conservative treatment
4. Being offered surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Not prepared to accept surgery
2. Requiring additional prolapse surgery
3. Undergone previous surgery for stress urinary incontinence
4. Not completed their families, i.e., will still want children
5. Unable or unwilling to give informed consent
6. Unwilling to participate in follow-up

Date of first enrolment

01/08/2004

Date of final enrolment

31/01/2006

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Department of Obstetrics & Gynaecology

Aberdeen

United Kingdom

AB25 2ZN

Sponsor information

Organisation

University of Aberdeen

ROR

<https://ror.org/016476m91>

Funder(s)

Funder type

University/education

Funder Name

University of Aberdeen

Alternative Name(s)

ABDN

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

NHS Grampian

Results and Publications

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? |
|-------------------------------|---------|--------------|------------|----------------|-----------------|
| Basic results | | | 06/12/2019 | No | No |