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

Submission date	Recruitment status
09/08/2010	No longer recruiting
Registration date	**Overall study status**
21/10/2010	Completed
Last Edited	**Condition category**
06/12/2019	Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes