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Randomised controlled trial of transvaginal tension-free vaginal tape-obturator (TVT-O) versus Monarc in treatment of urodynamic stress incontinence

Submission date
28/01/2006

Recruitment status
No longer recruiting

Registration date
16/03/2006

Overall study status
Completed

Last Edited
10/07/2017

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
05/Q1104/176

Study information

Scientific Title

Randomised controlled trial of transvaginal tension-free vaginal tape-obturator (TVT-O) versus Monarc in treatment of urodynamic stress incontinence

Study objectives
A comparison of two different ways of placing a suburethral tape (surgical procedure) to correct Urodynamic Stress Incontinence (USI). An assessment of the success rate and complications of the two procedures.

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Urodynamic Stress Incontinence (USI)

Interventions
Randomised controlled trial, patient allocation by random numbers with blocking

Surgery - either of two ways of placing a transobturator tape to correct the incontinence, tension-free vaginal tape-obturator (TVT-O) versus Monarc

Intervention Type
Procedure/Surgery

Primary outcome(s)
Objective and subjective cure of urodynamic stress incontinence

Key secondary outcome(s))
1. Operating time
2. Blood loss
3. Complications
4. Pain
5. Catheter use post-operatively
6. Voiding

Completion date
31/03/2008

Eligibility

Key inclusion criteria
1. Females having a primary continence procedure without other surgery
2. Diagnosis of USI
3. Completed course of physiotherapy
4. Completed family

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Previous continence or prolapse surgery
2. Neurological disease
3. Pregnancy
4. Urinary tract or vaginal infection
5. Detrusor overactivity
6. Voiding problem
7. Anticoagulant use

Date of first enrolment
01/04/2006

Date of final enrolment
31/03/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Countess of Chester Hospital
Chester
United Kingdom
CH2 1UL

Sponsor information

Organisation
Countess of Chester NHS Foundation Trust (UK)

ROR
https://ror.org/0149cpy58

Funder(s)

Funder type
Industry

Funder Name
Any expenses incurred will be covered by Gynecare and American Medical Systems who produce the two tapes

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