

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 16/03/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/07/2017	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Chester
United Kingdom
CH2 1UL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

Objective and subjective cure of urodynamic stress incontinence

Secondary outcome measures

1. Operating time
2. Blood loss
3. Complications
4. Pain
5. Catheter use post-operatively
6. Voiding

Overall study start date

01/04/2006

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

Age group

Adult

Sex

Female

Target number of participants

320

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

England

United Kingdom

Study participating centre

Countess of Chester Hospital

Chester

United Kingdom

CH2 1UL

Sponsor information

Organisation

Countess of Chester NHS Foundation Trust (UK)

Sponsor details

Liverpool Road

Chester

England

United Kingdom

CH2 1UL

Sponsor type

Hospital/treatment centre

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

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