

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

<b>Submission date</b> 28/01/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/03/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/07/2017	<b>Condition category</b> 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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Liverpool Road  
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## 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