

# Colposuspension or tension free vaginal tape with anterior repair for urinary incontinence and prolapse: a pilot study

**Submission date**

27/03/2006

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

17/05/2006

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

07/10/2009

**Condition category**

Urological and Genital Diseases

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

## Acronym

CARPET 1

## Study objectives

Retropubic colposuspension is more effective than a Tension free Vaginal Tape (TVT) insertion with anterior vaginal repair for the treatment of urodynamic stress incontinence and anterior vaginal prolapse.

Please note that, as of 08/09/2008, the anticipated end date of this trial has been updated from 30/04/2008 to 25/04/2008.

Please note that, as of 16/01/2009, the anticipated end date has been updated from 25/04/2008 to 30/09/2007 (end of recruitment). The last patient completed follow up in November 2007.

As of 19/01/2009, the target number of participants was amended from 150 (estimate) to 31 (actual number recruited). Please note that identification of the number of eligible and willing patients was one of the aims of this pilot trial.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved by Leicestershire, Rutland and Northamptonshire Ethics Committee Two, 29/11/2005, reference number: 05/Q2502 91

## Study design

Randomised patient preference trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Urodynamic stress incontinence/ vaginal prolapse (anterior)

### **Interventions**

1. Colposuspension
2. Suburethral tension free vaginal tape with anterior vaginal repair

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

1. Eligible patient numbers, by centre
2. Proportion of patients consenting to randomisation
3. Reasons for non-randomisation
4. Improvement in disease specific quality of life score at 6 weeks and 12 months

### **Secondary outcome measures**

1. Change in POP-Q score at 6 weeks and 12 months
2. Change in 24 hour pad test at 6 weeks and 12 months
3. Change in diary completed leakage episodes at 6 weeks and 12 months
4. Change in incidence of USI on urodynamics at follow up
5. Incidence of DOA on urodynamics at follow up at 12 months

### **Overall study start date**

01/05/2006

### **Completion date**

30/09/2007

## **Eligibility**

### **Key inclusion criteria**

Women with urodynamic stress incontinence (USI) and anterior vaginal prolapse of stage II or more assessed by Pelvic Organ Prolapse Quantification score (POP-Q)

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Female

### **Target number of participants**

31

### **Key exclusion criteria**

1. Detrusor overactivity (DOA) on urodynamics
2. Previous incontinence or prolapse surgery
3. Apical or posterior vaginal prolapse of stage II or more on POP-Q

**Date of first enrolment**

01/05/2006

**Date of final enrolment**

30/09/2007

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Robert Kilpatrick Clinical Sciences Building (RKCSB)

Leicester

United Kingdom

LE2 7LX

## Sponsor information

**Organisation**

University Hospitals of Leicester NHS Trust (UK)

**Sponsor details**

Research Office

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/02fha3693>

# Funder(s)

## Funder type

Government

## Funder Name

Medical Research Council (MRC) (UK) (grant ref: 73379)

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2009		Yes	No