ISRCTN34759911 https://doi.org/10.1186/ISRCTN34759911

# 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

**Registration date**
17/05/2006

**Overall study status**
Completed

**Last Edited**
07/10/2009

**Condition category**
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**
UHL 9967

## 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

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Urodynamic stress incontinence/ vaginal prolapse (anterior)

## Interventions
1. Colposuspension
2. Suburethal tension free vaginal tape with anterior vaginal repair

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome(s)

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

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### 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
United Kingdom

England

**Study participating centre**
**Robert Kilpatrick Clinical Sciences Building (RKCSB)**
Leicester
United Kingdom
LE2 7LX

# Sponsor information

**Organisation**
University Hospitals of Leicester NHS Trust (UK)

**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

**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? |
|---|---|---|---|---|---|
| Results article | results | 01/12/2009 | | Yes | No |