

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

Contact name

Dr Douglas Tincello

Contact details

Robert Kilpatrick Clinical Sciences Building (RKCSB)

Leicester Royal Infirmary

P.O. Box 65

Leicester

United Kingdom

LE2 7LX

+44 (0)116 252 5813

dgt4@le.ac.uk

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. Suburethral 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, Medical Research Committee and Advisory 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