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	Recruitment status	[_] Prospectively registered
27/03/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/05/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/10/2009	Urological and Genital Diseases	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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. Suburethal 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
Leicester General Hospital
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW
+44 (0)116 258 4109
nicola.turner@uhl-tr.nhs.uk

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?
Results article	results	01/12/2009		Yes	No