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Posterior Intravaginal Slingplasty (Infracoccygeal Sacropexy) with uterine preservation Vs Vaginal Hysterectomy with Posterior Intravaginal Slingplasty in women with at least grade II uterovaginal prolapse.

Submission date	Recruitment status	[_] Prospectively registered
28/09/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/09/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/10/2016	Urological and Genital Diseases	[_] Record updated in last year

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
N0035188760

Study information

Scientific Title
Posterior Intravaginal Slingplasty (Infracoccygeal Sacropexy) with uterine preservation Vs Vaginal Hysterectomy with Posterior Intravaginal Slingplasty in women with at least grade II uterovaginal prolapse.

Study objectives
To compare 2 procedures - Posterior Intravaginal Slingplasty & Vaginal Hysterectomy (standard operation) for uterovaginal prolapse in terms of efficacy, intra & postoperative morbidity, postoperative pain/discomfort, hospital stay, patients satisfaction, quality of life & surgical goals.

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

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Prolapse

Interventions
Educational randomised controlled trial - 2 arms:
Posterior Intravaginal Slingplasty (Infracoccygeal Sacropexy) with uterine preservation Vs Vaginal Hysterectomy with Posterior Intravaginal Slingplasty

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Pelvic organ prolapse quantification scale
2. Patient centered goals
3. Pelvic organ prolapse quality of life score
4. Surgical goals

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/08/2005

Completion date
01/04/2007

Eligibility

Key inclusion criteria
124 female patients (62 in each arm) with at least grade II uterovaginal prolapse with or without other vaginal wall defects.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
124

Key exclusion criteria
Patients with previous surgery for prolapse can be included.

Date of first enrolment
16/08/2005

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant Obs & Gynae
Basildon
United Kingdom
SS16 5NL

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Basildon and Thurrock University Hospitals NHS Trust

Funder Name
NHS R&D Support Funding

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