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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

Protocol serial number
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

Study type(s)
Treatment

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(s)
1. Pelvic organ prolapse quantification scale
2. Patient centered goals
3. Pelvic organ prolapse quality of life score
4. Surgical goals

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

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

Funder(s)

Funder type
Government

Funder Name
Basildon and Thurrock University Hospitals NHS Trust

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration