

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 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 28/10/2016	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

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