

Total versus subtotal hysterectomy: a prospective, randomised, multi-centre study of the effects on urinary, sexual and bowel function

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/11/2010	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

REC00076

Study information

Scientific Title

Study objectives

To determine whether subtotal abdominal hysterectomy results in better bladder, bowel or sexual function than total abdominal hysterectomy

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: Menstrual disorders

Interventions

Subtotal hysterectomy vs total hysterectomy

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Measures of bladder, bowel and sexual function at 12 months

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1996

Completion date

01/01/1999

Eligibility

Key inclusion criteria

Women referred for hysterectomy because of benign disease; most of the women were premenopausal

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

Key exclusion criteria

Aged over 60 years, suspected cancer, a body weight that exceeded 100 kg, previous pelvic surgery, known endometriosis, abnormal cervical smears, symptomatic uterine prolapse, symptomatic urinary incontinence

Date of first enrolment

01/01/1996

Date of final enrolment

01/01/1999

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St George's Healthcare NHS Trust
London

United Kingdom
SW7 0QT

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

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.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive London

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	24/10/2002		Yes	No