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	 Prospectively registered Protocol
Registration date 23/01/2004	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 18/11/2010	Condition category Urological and Genital Diseases	Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Dr Isaac Manyonda

Contact details

St George's Healthcare NHS Trust Department of Obstetrics & Gynaecology St George's Hospital London United Kingdom SW7 0QT imanyond@sghms.ac.uk

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