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A randomised trial to assess the effectiveness, costs and cost-effectiveness of laparoscopic, vaginal and abdominal hysterectomy

Submission date 25/04/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/04/2003	**Overall study status** Completed	
Last Edited 21/08/2009	**Condition category** Surgery	

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
HTA 94/16/03

Study information

Scientific Title

Study objectives
The project aims to determine by means of a randomised controlled trial the operative problems, benefits, complications and costs of laparoscopic hysterectomy compared to those associated with both conventional abdominal and vaginal methods of hysterectomy. It will be a multicentre study of 1800 cases collected over an 18 month period by surgeons with differing skill levels from a variety of centres. The study will last for 3 years and will include follow-up assessments at 6 weeks, 3 months, 6 months, and 1 year. The effects of training and experience on outcome will be determined. The objectives of the study are to define the place of laparoscopic hysterectomy in gynaecology and to identify the short-term advantages and disadvantages of this approach for both the patients and the NHS.

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: Other urological and genital disease

Interventions
Please note that, as of 25 January 2008, the end date of this trial was updated from 31 August 1999 to 28 February 2001.

Interventions:
Laparoscopic, vaginal or abdominal hysterectomy

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Operative problems, benefits, complications and costs

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/09/1996

Completion date
28/02/2001

Eligibility

Key inclusion criteria
Not provided at time of registration.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1800

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/09/1996

Date of final enrolment
28/02/2001

Locations

Countries of recruitment
Australia

South Africa

United Kingdom

Study participating centre
School of Women's and Infants' Health
Perth
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Sponsor information

Organisation
Department of Health (UK)

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Quarry House
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name

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	17/01/2004		Yes	No