

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
Registration date 25/04/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/08/2009	Condition category Surgery	☐ Individual participant data

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

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

Study type(s)

Treatment

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(s)

Operative problems, benefits, complications and costs

Key secondary outcome(s))

Not provided at time of registration.

Completion date

28/02/2001

Eligibility

Key inclusion criteria

Not provided at time of registration.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

Australia

South Africa

Study participating centre

School of Women's and Infants' Health

Perth

Australia

6008

Sponsor information

Organisation

Department of Health (UK)

ROR

<https://ror.org/03sbpja79>

Funder(s)**Funder type**

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications**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