

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

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/08/2009	<b>Condition category</b> Surgery	<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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### Contact details

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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?
<a href="#">Results article</a>	results	17/01/2004		Yes	No