

# The operator effect on the ultrasound diagnosis of ovarian tumours: a prospective randomised study

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/05/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr D Jurkovic

### Contact details

Department of Obstetrics and Gynaecology  
King's College Hospital  
Denmark Hill  
London  
United Kingdom  
SE5 9RS

## Additional identifiers

### Protocol serial number

N0116148369

## Study information

### Scientific Title

**Study objectives**

To see whether an ultrasound scan performed in an expert centre could reduce the number of major surgical procedures performed in the management of ovarian pathology.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Prospective randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Ovarian cancer

**Interventions**

This will be a randomised prospective study, including all women who attend the Rapid Access Clinic at Guy's hospital with a suspected pelvic mass. An information leaflet about the study will be given to all those patients referred with a suspected pelvic mass. If an ultrasound is indicated and if these patients consent to participate in the study and they meet the inclusion criteria, they will be randomised by a sealed envelope system to having their scan at Guy's & St Thomas' (routine), or at King's (expert).

The result of the scan will be reviewed by the lead consultant who will decide on the method of management of these patients based on the result of the scan report and an agreed management protocol. Findings at the operation and that of the histological investigation will be recorded. Any additional tests performed to aid the diagnosis made on ultrasound will be recorded as well. We will compare the above data between the two groups i.e. those who had routine scanning and those who had expert scanning.

In women who undergo conservative management, a follow up scan and a blood test will be carried out at regular intervals and any changes in diagnosis or plan of management will be recorded. The cost of different methods of management will be assessed and compared: cost of bed occupancy, price of operation, theatre time, short term and long term recovery cost. All the data collected will be stored on Microsoft Excel spreadsheets, on a disk and will be password protected. Only those directly involved in the study will be able to access these data.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

The main endpoint measure will be the number of invasive operative tests performed in each arm of the study.

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

01/07/2006

## Eligibility

**Key inclusion criteria**

Women who attend the Rapid Access Clinic at Guy's hospital with a suspected pelvic mass.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

19/04/2004

**Date of final enrolment**

01/07/2006

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Department of Obstetrics and Gynaecology

London

United Kingdom

SE5 9RS

# Sponsor information

## Organisation

Department of Health

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Kings College Hospital NHS Trust R&D Consortium (UK)

### Funder Name

Own Account NHS R&D support funding (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	01/02/2008		Yes	No