

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

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

19/04/2004

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

Age group

Adult

Sex

Female

Target number of participants

165

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

England

United Kingdom

Study participating centre

Department of Obstetrics and Gynaecology

London

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Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

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SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

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

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	01/02/2008		Yes	No