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

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 17/05/2012	**Condition category** Cancer	

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
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
United Kingdom
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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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