

Comparison of two ultrasound assessment tools for the diagnosis of ovarian tumours in asymptomatic post-menopausal women

Submission date 26/01/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/03/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/09/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-trial-comparing-2-ways-examining-managing-ovarian-swellings>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Comparison of intervention rates for the Risk of Malignancy Index (RMI) and the Royal College of Obstetricians and Gynaecologists green top guideline number 34 (October 2003) on postmenopausal cysts with simple ultrasound scan rules by the International Ovarian Tumour Analysis Group (IOTA): a randomised controlled trial

Study objectives

Most asymptomatic ovarian cysts/adnexal masses detected on ultrasound scan are benign. In these women, an operation to remove the cyst is not necessary. By avoiding surgery women are not exposed to surgical and anaesthetic complication and their care is more cost-effective. Postmenopausal women are more likely to suffer from other medical problems such as diabetes and high blood pressure, which increase operative and anaesthetic risks.

We do not expect to find a significant difference in the sensitivities for the diagnosis of ovarian cancer between the two protocols. We do expect, however, that the specificity of the new protocol will be better, which should translate into lower intervention rates.

This study hopefully will show that use of the Simple Rules and conservative management will reduce intervention rate without significantly increasing risk to the patients. This would increase patient safety and result in significant savings for the NHS.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North London Research Ethics Committee, 30/09/2010 ref: 10/H0724/48

Study design

Interventional single centre 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

Asymptomatic ovarian cysts or adnexal tumours in postmenopausal women

Interventions

Women with presumed benign cysts will be observed over the following year in 3-4 monthly intervals in order to detect any change in appearance or increase in size, which would be suspicious of malignancy. Any suspicion of malignant change, however, would trigger a surgical intervention.

Patients will be randomized by pulling sequential sealed envelopes. These envelopes have been prepared from a computer generated randomization list created by the statistician.

1. The Risk of Malignancy Index (RMI) and the Royal College of Obstetricians and Gynaecologists green top guideline number 34 (October 2003) on postmenopausal cysts
2. Simple ultrasound scan rules by the International Ovarian Tumour Analysis Group (IOTA)

In both arms of the study women will be classified into three groups:

1. Presumed malignant cyst
2. Presumed benign cyst
3. Cysts of indeterminate nature

The management strategies will be identical in both arms:

1. Women with presumed malignancies will have surgery or management in a tertiary cancer centre
2. Women with presumed benign cysts will be managed expectantly
3. Women with indeterminate findings will be operated on in local cancer units.

Once the scan (+/- blood test) is done all assessments place patient into 1 of 3 categories. The categories are Benign, Indeterminate risk and Malignant. Those with benign tumours are offered 4 monthly scans for 1 year, those with indeterminate tumours are offered surgery in her consultants team and those with malignant tumours are referred to the tertiary oncology team.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The number of surgical interventions in the two study groups

Secondary outcome measures

1. Number of staging laparotomies
2. Diagnostic accuracy of the two protocols
3. Number of blood tests to measure tumour markers
4. Number of surgical complications

Overall study start date

01/04/2011

Completion date

31/03/2014

Eligibility

Key inclusion criteria

1. Postmenopausal women found to have an ovarian cyst / adnexal mass
2. Postmenopausal women known to have an ovarian cyst / adnexal mass and referred for an opinion
3. Women who do not have any significant pain or bloating not explained but other pathology.

Postmenopausal women are defined as those who have had 1 year of spontaneous amenorrhoea above or at the age of 40 where no illness or medication may have caused the amenorrhoea or those above or at the age of 50 who have had a hysterectomy.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

148

Key exclusion criteria

1. Pre-menopausal women
2. Women with pain localised to the area of the cyst or the lower abdomen
3. Women below 40 or above 80 years of age
4. Written informed consent declined or patients unable to give consent
5. Women not medically fit for surgery
6. Women with simple unilateral unilocular cysts of less than 2cm

Date of first enrolment

01/04/2011

Date of final enrolment

31/03/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University College London Hospitals
London
United Kingdom
NW1 2BU

Sponsor information

Organisation

University College London Hospital NHS Foundation Trust

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.uclh.nhs.uk/>

ROR

<https://ror.org/042fqyp44>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University College London Hospitals NHS Foundation Trust

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	28/02/2017	22/01/2019	Yes	No
Plain English results			30/09/2020	No	Yes