ISRCTN89034131 https://doi.org/10.1186/ISRCTN89034131

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/03/2012	**Overall study status** Completed	
Last Edited 30/09/2020	**Condition category** Cancer	

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
Miss Natalie Nunes

Contact details
University College London Hospitals
Clinc 3
Elizabeth Garrett Anderson Building
235 Euston Road
London
United Kingdom
NW1 2BU

Additional identifiers

Protocol serial number
10/H0724/48

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

Study type(s)
Diagnostic

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 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(s)
The number of surgical interventions in the two study groups

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

Study participating centre
University College London Hospitals
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College London Hospital NHS Foundation Trust

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University College London Hospitals NHS Foundation Trust

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?
Results article	results	28/02/2017	22/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			30/09/2020	No	Yes