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Phase 4 of the International Ovarian Tumour Analysis study group: To compare the referral pattern and cost-effectiveness of using Risk of Malignancy Index (RMI) versus Logistic Regression model (LR2) to diagnose adnexal masses prior to surgery

Submission date 16/12/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 04/01/2013	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 30/11/2017	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-different-ways-of-working-out-whether-an-ovarian-cyst-is-cancerous-iota4

Contact information

Type(s)
Scientific

Contact name
Prof Tom Bourne

ORCID ID
http://orcid.org/0000-0003-1421-6059

Contact details
Early Pregnancy and Acute Gynaecology Scanning Unit
Queen Charlotte's and Chelsea Hospital
Imperial College London
Hammersmith Campus
Du Cane Road
London
United Kingdom
W12 0HS

+44 (0)20 8383 5131
t.bourne@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10/H0707/28

Study information

Scientific Title
Randomised controlled trial to compare the referral pattern and cost-effectiveness of using RMI versus LR2 to diagnose adnexal masses prior to surgery

Acronym
IOTA4

Study objectives
This comparison will show that triaging patients using logistic regression model (LR2) is likely to be superior or inferior compared to the currently standard protocol based on the Risk of Malignancy Index (RMI). This may render the preoperative management of adnexal masses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. West London ethics committee, 09/2010, ref: 10/H0707/28
2. Imperial College London and Imperial College Healthcare NHS Trust, 9/12/2010, R&D reference number: BOUT3001

Study design
Prospective multicentre 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 contact a.sayasneh@imperial.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Ovarian cancer

Interventions
Control arm: diagnosis using the RMI
The RMI is a scoring system based on a logistic regression model to diagnose adnexal masses as benign or malignant (Jacobs et al, 1990). The RMI equals U*M*CA125, where U is the ultrasound score, M the menopausal status score, and CA125 is the level of serum CA125 in u/ml. The ultrasound score is based on five characteristics: multilocular cyst, evidence of solid areas, evidence of metastases, presence of ascites, and bilateral lesions. U equals 0 if none of these characteristics are present, 1 if one characteristic is present, and 3 if two or more characteristics are present. M equals 1 for premenopausal and 3 for postmenopausal women.

Intervention arm: diagnosis using LR2
LR2s predictors are:
1. Age of the patient (years)
2. The presence of ascites (yes=1, no=0)
3. The presence of blood flow within a papillary projection (yes=1, no=0)
4. Largest diameter of the solid component (expressed in mm but with no increase above 50 mm)
5. Irregular internal cyst walls (yes=1, no=0), and
6. The presence of acoustic shadows (yes=1, no=0). The estimated probability (risk) of malignancy equals 1/(1+e-z), where z = 5.3718 + 0.0354(1) + 1.6159(2) + 1.1768(3) + 0.0697(4) + 0.9586(5) 2.9486(6). The probability will be multiplied by 100 to yield the percentage risk.

We estimate to enroll the first patient in April 2010, the last patient in July 2012, and the last follow-up visit in July 2013.

Study visits
If surgery is necessary, the day of surgery is time zero with follow-up visits at 2 weeks, 6 weeks, and 12 months from surgery.

If surgery is not necessary, the diagnosis (i.e. the lead clinicians final decision regarding treatment) is time zero with follow-up visits 6 weeks, 4 months, and 12 months later.

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
Histological diagnosis (benign or malignant) for patient who undergo surgery. Three follow up findings over one year for conservative management patients.

Secondary outcome measures

Effectiveness related variables
1. The percentage of patients with a borderline/invasive mass assigned to the moderate or high risk groups)
2. The actual safety and efficiency based on the real-life referral pattern observed in both study arms (i.e. percentage of patients with a benign mass that are conservatively managed or received local surgery, and the percentage of patients with a borderline or invasive mass that are referred to the cancer unit or cancer centre)
3. The percentage of patients with different types of surgical interventions
4. The median length of hospital stay
5. Health-related quality of life

Overall study start date
01/09/2010

Completion date
01/07/2013

Eligibility

Key inclusion criteria
1. Women (non pregnant women above the age of 16) with any abnormal morphology of the ovary evident on an ultrasound scan performed for any clinical symptom
2. Signed and dated informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
400

Key exclusion criteria
1. Premenopausal women with functional or simple cysts less the 3 cm mean diameter
2. Pregnant women

Date of first enrolment
01/09/2010

Date of final enrolment
31/05/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Queen Charlotte's and Chelsea Hospital
Early Pregnancy and Acute Gynaecology Scanning Unit
Du Cane Rd
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Imperial College London and Imperial College Healthcare NHS Trust (UK)

Sponsor details
Becky Ward
Research Governance Manager
Joint Research Compliance Office
Room 5L10A
5th Floor, Lab Block
Charing Cross Hospital
Fulham Palace Road
London
England
United Kingdom
W6 8RF
+44 (0)20 3311 0205
becky.ward@imperial.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.imperial.ac.uk/clinicalgoveranceoffice

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Imperial College Healthcare NHS Trust (UK)

Alternative Name(s)
Imperial NHS, imperialnhs, Imperial College Healthcare NHS Trust | London

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study has been published and disseminated as an open access publication as a PhD thesis with methods/results/discussion and conclusion

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?
Thesis results	Thesis available at:	01/07/2015		No	No