

MR in ovarian cancer

Submission date 17/11/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 30/11/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 20/02/2024	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-using-mpmri-scans-in-staging-and-treatment-decisions-for-ovarian-cancer-mroc>

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Type(s)

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Scientific

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Additional identifiers

Protocol serial number

C/33/2014

Study information

Scientific Title

The impact of multiparametric MRI on the staging and management of patients with suspected or confirmed ovarian cancer

Acronym

MROC

Study objectives

The aim of this study is to evaluate the possibility of mpMRI providing an improved radiological assessment for the classification and delineation of the extent of disease for patients with suspected ovarian cancer compared to standard of care CT assessment, potentially facilitating more accurate decisions regarding patient management by the MDT.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Committee: London – City Road and Hampstead, 03/12/2015, REC Ref: 15/LO/1904

Study design

Multi-centre diagnostic accuracy trial

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Ovarian cancer

Interventions

645 women with suspected or confirmed OC will be recruited onto the study and will have an mpMRI scan in addition to the standard of care CT. After all the scans have been obtained, the MDT at the site (the medical team who make decisions about a patients care) will then determine the stage and treatment plan for the patient based upon the CT alone, as per

standard practice guidelines. Any critical findings from the mpMRI will be revealed to the MDT after they have made an initial decision; the patient will then progress with treatment, as decided.

The local MDT will then meet again for a further two meetings. In the second meeting they will produce theoretical treatment plans based upon the mpMRI alone and then another using a combination of the mpMRI and CT scan. This will not affect how the patient is treated. The third meeting will be 6 months after the patient was first enrolled onto the trial. At this meeting all available clinical and imaging information will be reviewed and the MDT will determine what stage the patient was at and what the optimal treatment plan would have been.

Anonymised copies of the CT and mpMRI scans will also be sent to MDTs at two other external NHS hospitals. They will hold three separate meetings that will occur three months apart. They will form theoretical treatment plans based upon the CT alone, mpMRI alone and CT and mpMRI combined and the order in which they report them will be randomly allocated. These treatment plans will not have any effect on patient management. The purpose of doing this is to compare how a patient's treatment is decided based on whether MDTs are looking at the CT scan, the mpMRI scan or both and also to see if these decisions are the same between different MDTs.

During the study, patients will only attend one extra appointment for the mpMRI, all other data will be provided by their medical records and the MDTs. Participants will also be given the option to donate tissue and blood samples, which would be obtained during surgery at participating hospitals who routinely collect fresh-frozen tissue.

Intervention Type

Other

Primary outcome(s)

Comparison of the diagnostic accuracy in detecting advanced cancer stage based on radiological staging of women with suspected or confirmed ovarian cancer between mpMRI with CT and CT alone

Key secondary outcome(s)

1. Difference in proportion of patients avoiding unsuccessful patient management mostly resulting from (unnecessary) cancer surgery. mpMRI and CT will be compared against the reference standard for patient management decisions to determine unsuccessful treatment
2. Comparison of image findings determining surgical resectability and the MDT decisions determining surgical resectability, per patient
3. Comparison of incremental cost and cost effectiveness accounting for categorisation into final surgical outcome, treatment costs & patient outcomes
4. Difference in sensitivity and specificity of peritoneal disease of diagnostic accuracy, per patient and per location
5. Comparison of MDT plans between local and external MDTs for treatment choice, ITU stay, length of operation, surgical expertise needed, per patient

Sub-Study Objectives:

1. Inter-observer agreement of mpMRI interpretation/reading for accurate diagnosis of referral for sites of disease and cancer stage; per patient and per location
2. Comparison of mpMRI to conventional MRI (analyse for primary outcome and secondary outcomes 1 and 2 only) in order to determine incremental benefit

Completion date

08/02/2023

Eligibility

Key inclusion criteria

1. Written (signed and dated) informed consent* prior to mpMRI scan^ and judged capable of co-operating with study requirements during treatment and follow-up
2. Aged 18 years or over
3. Suspected ovarian, fallopian tube or primary peritoneal cancer. This can be contingent on imaging findings (either on ultrasound or CT) and/or a Risk Malignancy Index Score (RMI) greater than 250
4. Being considered for up-front surgery or for interval debulking surgery following neoadjuvant chemotherapy (after 3 to 5 cycles) via the "NHS Cancer Pathway"
5. Considered fit for surgery (by MDT or patient's surgeon)

*A patient can be enrolled based on verbal consent with written consent to be obtained prior to the mpMRI scan

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Total final enrolment

648

Key exclusion criteria

1. Known contraindication to MRI (e.g. claustrophobia, ferrous implants, cardiac pacemaker, inability to lie flat)
2. Known pregnancy
3. Medical or psychiatric illness that renders the patient unsuitable or unable to give informed consent
4. Unable to undergo a CT scan with IV contrast due to allergy, renal failure or any other cause

Date of first enrolment

01/03/2016

Date of final enrolment

30/12/2020

Locations

Countries of recruitment

United Kingdom

England

Scotland

Study participating centre

Hammersmith Hospital

Du Cane Road

London

United Kingdom

W12 0NN

Study participating centre

The Royal Marsden Hospital

Fulham Road

London

United Kingdom

SW3 6JJ

Study participating centre

University College Hospital

235 Euston Road

London

United Kingdom

NW1 2BU

Study participating centre

Beatson West of Scotland Cancer Centre

1053 Great Western Road

Glasgow

United Kingdom

G12 0YN

Study participating centre

Royal Sussex County Hospital

Eastern Road

Brighton

United Kingdom
BN2 5BE

Study participating centre

Maidstone Hospital

Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre

Kent and Canterbury Hospital

Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre

Kingston Hospital

Galsworthy Road
Kingston-upon-Thames
United Kingdom
KT2 7QB

Study participating centre

Liverpool Women's Hospital

Crown Street
Liverpool
United Kingdom
L8 7SS

Study participating centre

Clatterbridge Cancer Centre - Aintree

Lower Lane
Fazakerley
Liverpool
United Kingdom
L9 7AL

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
Croydon University Hospital
530 London Road
Croydon
United Kingdom
CR7 7YE

Study participating centre
Epsom Hospital
Dorking Road
Epsom
United Kingdom
KT18 7EG

Study participating centre
St Helier Hospital
Wrythe Lane
Sutton
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Gloucestershire NHS Foundation Trust
Trust Headquarters
Alexandra House
Cheltenham General Hospital

Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
Gateshead Health NHS Foundation Trust
Elisabeth Queen Hospital
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrooke's Hospital
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
London North West University Healthcare NHS Trust
Watford Road
Harrow
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HA1 3UJ

Sponsor information

Organisation
Imperial College London (UK)

ROR
<https://ror.org/041kmwe10>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Andrea Rockall.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version v4.3	04/09/2020	02/12/2020	No	No