ISRCTN51246892 https://doi.org/10.1186/ISRCTN51246892

MR in ovarian cancer

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

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

Contact information

Type(s)
Public

Contact name
Miss Amanda Bigault

Contact details
Cancer Research UK Imperial Centre: Clinical Trials Section / Imperial Clinical Trials Unit – Cancer
Department of Surgery and Cancer
Imperial College London
3rd Floor Radiotherapy Building
Hammersmith Hospital Campus
Du Cane Road
London
United Kingdom
W12 0NN
+44 (0)20 7589 5111
mroc@imperial.ac.uk

Type(s)
Scientific

Contact name
Prof Andrea Rockall

Contact details
1st Floor, ICTEM building,
Hammersmith Hospital Campus

Du Cane Road
London
United Kingdom
W12 0NN

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 patients 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 mpMR 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
United Kingdom
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
Participant information sheet	Participant information sheet version v4.3	11/11/2025	11/11/2025	No	Yes
Protocol file		04/09/2020	02/12/2020	No	No