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MAchine Learning in whole Body Oncology

Submission date 08/07/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 28/08/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 05/09/2023	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Magnetic resonance imaging (MRI) is a type of scan that produces detailed images of the inside of the body. Whole body magnetic resonance imaging (MRI) is being increasingly used to assess the amount of tumours in patients with metastatic cancer (cancer that has spread). However, whole body MRI has limitations in its diagnostic performance. Moreover, it is time-consuming to report a whole body scan, even for experienced readers. Machine learning is the process of training a computer to make decisions, based on already existing data. The aim of this study is to develop and test machine learning methods, applied to whole body MRI, to improve the diagnostic performance of whole body MRI and reduce the amount of time it takes for a radiologist to read a whole body MRI scan.

Who can participate?
This is a study limited to working with data from completed or currently recruiting studies. The study is divided into three Phases. In Phase 1 whole body MRI scans from healthy adult volunteers will be used. In Phases 2 and 3 data from child and adult patients with metastatic cancer will be used.

What does the study involve?
The MRI scans' diagnostic performance and radiologists' reading time will be compared with and without the assistance of the developed machine learning methods.

What are the possible benefits and risks of participating?
There are no perceived risks or direct benefits to the participants, as the application of the machine learning methods will take place after their clinical imaging has taken place. Future potential benefits include improvements in the diagnostic accuracy of whole body MRI scans, which could improve the initial cancer staging process, by improving the accurate detection of metastatic disease and reducing staging errors that could lead to unnecessary tests. Undergoing a single highly effective test for staging would also avoid the need for multiple patient visits to hospital.

Where is the study run from?
The study is run and led by the Imperial College Comprehensive Cancer Imaging Centre (C.C.I.C.)

and Department of Computing. Participating centres (providing imaging data and radiological reading support) include the following: University College London (UCL) and UCL Hospital (UCLH), King's College London and the Royal Marsden Hospital (RMH).

When is the study starting and how long is it expected to run for?
From February 2015 to July 2018.

Who is funding the study?
National Institute of Health Research (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
C/32/2014

Study information

Scientific Title
Development and evaluation of machine learning methods in whole body MR with diffusion weighted imaging for staging of patients with cancer

Acronym

MA.L.I.B.O.

Study objectives
The use of machine learning can improve the diagnostic performance of whole body MRI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IC REC for Phases 2 and 3: 15IC2647

Study design
Observational study (study limited to working with data)

Primary study design
Observational

Secondary study design
Study limited to working with data

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Cancer

Interventions
Research will be carried out at Imperial College London in collaboration with the teams of main studies (NIHR STREAMLINE (colon & lung cancer patients) and CRUK MELT (lymphoma patients)) who have recruited all the patients for diffusion weighted imaging (WB-DW-MR) datasets. The proposed study has three stages: firstly, WB-DW-MR from 50 healthy volunteers will be used to develop the machine learning (ML) method for automatic recognition of normal appearances. Secondly, the ML method will be tested on 150 WB-MR scans from the main studies, in whom the different sites of disease have already been confirmed. The ML method will be refined by radiologists who will identify the correct sites of disease and find ML errors. This will be used to improve the ML method. Thirdly, the refined ML method will be tested in a second group of 169 patients from the main studies to see if the technique can improve radiology reporting by improving diagnostic accuracy (DA) and reading time (RT).

Intervention Type
Other

Primary outcome measure

Per site sensitivity and specificity of MRI for nodal and extra-nodal sites and concordance in final disease stage with the multi-modality reference standard (at staging). The reference standard for the MELT study is contemporaneous MDT with all other staging eg PET CT and CT at the time of diagnosis and initial staging,

Secondary outcome measures
1. Inter-observer agreement for MR radiologists
2. Evaluation of different MRI sequences on diagnostic accuracy
3. Simulated effect of MRI on clinical management

Overall study start date
01/02/2015

Completion date
30/07/2018

Eligibility

Key inclusion criteria
As per each source (contributing) study (http://www.isrctn.com/ISRCTN50436483, http://www.isrctn.com/ISRCTN43958015, https://clinicaltrials.gov/ct2/show/NCT01459224)

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
217

Key exclusion criteria
As per each source (contributing) study (http://www.isrctn.com/ISRCTN50436483, http://www.isrctn.com/ISRCTN43958015, https://clinicaltrials.gov/ct2/show/NCT01459224)

Date of first enrolment
01/10/2015

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College, London - Hammersmith Campus
United Kingdom
W12 0NN

Sponsor information

Organisation
Imperial College, London - Joint Research Compliance Office

Sponsor details
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Sponsor type
University/education

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

Publication and dissemination plan
We plan to disseminate our study findings in the appropriate conventional, peer-reviewed conference presentations, including high impact radiology, computing sciences, MR physics and clinical conferences (in abstract form as scientific presentations at radiology conferences, as well as computing sciences conferences) and as full original scientific peer-reviewed publications in high impact factor scientific journals. The co-applicants have significant experience in presenting and publishing in their own fields.The study findings may have an important impact on the use of WB-DW-MRI in cancer and the subsequent patient management and therefore we intend to present this information to the appropriate forum at the Royal Colleges of Radiologists, International Cancer Imaging Society and MIUA (Medical Image Understanding and Analysis). We will present the findings at national cancer meetings, including the NCRI conference. We hope to have scientific abstracts accepted for publication at the MICCAI (Medical Image Computing and Computer Assisted Intervention) and the clinical imaging conferences ISMRM (International Society of Magnetic Resonance in Medicine) and RSNA (Radiological Society of North America). Dissemination of the project outcomes will be vital to the NHS and public organisations who may be able to benefit. We will use link with national cancer networks and disseminate findings through any relevant NHS clinical care groupings.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/06/2023	05/09/2023	Yes	No