ISRCTN23068310 https://doi.org/10.1186/ISRCTN23068310

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 02/09/2025	**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?
Prof Andrea G. Rockall
a.rockall@imperial.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Andrea Rockall

Contact details
Department of Radiology
Imperial College NHS Healthcare Trust
Hammersmith Hospital Campus
London
United Kingdom
W12 0NN
+44 (0)786 658 5476
a.rockall@imperial.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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,

Key secondary outcome(s))
1. Inter-observer agreement for MR radiologists
2. Evaluation of different MRI sequences on diagnostic accuracy
3. Simulated effect of MRI on clinical management

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

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
438

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
United Kingdom

England

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

Sponsor information

Organisation
Imperial College, London - Joint Research Compliance Office

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

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
Results article		01/10/2024	02/09/2025	Yes	No