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To test artificial intelligence (AI)-assisted magnetic resonance imaging (MRI) in detecting disease activity in Multiple Sclerosis, and to determine whether AI impacts MRI review, treatment decisions, costs, and follow-up care

Submission date
21/02/2025

Recruitment status
Recruiting

Registration date
28/02/2025

Overall study status
Ongoing

Last Edited
28/02/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a chronic, disabling disease driven by an abnormal immune response to the central nervous system. Over 120,000 people live with MS in the UK costing the NHS more than £1billion/year. Early disease modifying treatment (DMT) is part of the standard of care for people with MS (pwMS). Unless effectively treated, MS leads to significant disability, and in most cases associated care costs. However, whether any of the currently licensed fifteen DMTs is effective in an individual person with MS is unpredictable. Effective treatment monitoring is essential to (i) detect signs of disease activity before the individual suffers its effects and (ii) enable early switching to a different, hopefully (more) effective, DMT. In clinical practice, regular magnetic resonance imaging (MRI) is the only established tool for DMT efficacy monitoring. However, detecting the often-subtle changes by inspecting MRI scans is time consuming, tiring and therefore error-prone. Icobrain-ms is a validated AI technology enabling quantification of MRI datasets, summarising findings in a structured electronic report as well as annotated images highlighting areas of change that help guide assessment. Icobrain-ms complements visual assessment of MRI scans and helps the clinician to decide whether a change in DMT is warranted.

Who can participate?
Patients age over 18 with Clinically Isolated Syndrome suggestive of demyelination (CIS) or definitive diagnosis of MS will be recruited from the neuro-inflammation services of the participating clinical trial sites. They must also be either on a DMT or under consideration for DMT. Potential participants will be identified by the Principal Investigator (PI) and other members of the clinical care teams from the caseload of patients under the care of each site's hospital or Trust. These will be patients that are due their MRI brain scans as per standard of care. The single exclusion criterion is patient with MS participating in a randomised controlled CTIMP. Due to the severity of the disease, some participants may have some degree of cognitive impairment and may be considered as vulnerable participants as per the NHS England

safeguarding guidelines. Whilst vulnerable participants will be included in this study, all participants, including those who are vulnerable, must have capacity.

What does the study involve?
Patients from 3 hospitals in the UK will be approached to take part in the study. 1336 participants will take part. The clinical usefulness of icobrain ms software will be assessed by evaluating the detection of disease activity (as defined by new/expanding lesions): what proportion of patients have disease activity detected when icobrain ms is being employed, alongside the visual assessment, compared to SoC assessment by a (neuro)radiologist.
The primary outcome is to identify difference in disease activity between the interventional arm and SoC based on baseline-year 1 and/or, where available, retrospective-baseline. We will also investigate:
- The clinical usefulness of icobrain ms.
- The contribution of icobrain ms to treatment initiation or switch decisions.
- The impact of icobrain ms on patient outcomes.
- The efficiency of radiologists reporting MRI scans.
- The cost-effectiveness of icobrain ms

All the elements of the patients' treatment will follow the normal care pathway for all MS patients at the hospital.

What are the possible benefits and risks of participating?
Icobrain ms is a medical device intended for automatic labelling, visualisation and quantification of brain structures from a set of MRI images. The icobrain ms software will not be making independent 'decisions' on behalf of patient care, as expert neuro-radiologists will be involved with every scan interpretation. Therefore, there are no direct risks and harms associated with using icobrain ms and the device itself has no direct impact on the patient.

The possible benefits are:
1. The optimization and standardisation of brain scans acquisitions.
2. High accuracy and reliability: icobrain ms delivers accurate quantitative measurements of brain lesions and brain atrophy to monitor clinical changes.
3. Increased consistency of radiology report: icobrain ms creates more structured radiology reports increasing reader consistency for greater reliability of imaging results.
4. Reduced Health inequalities: icobrain ms can help to reduce health inequalities that are due to variation in MS expertise and sub-specialisation across the NHS.
5. Improve patient outcomes and reduce total cost of care: icobrain ms provides clinicians with valuable insights on disease activity, accelerating time to optimal treatment, which can improve patient outcomes and a reduction of health and other care costs associated with neurological disability.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
May 2022 to April 2027

Who is funding the study?
Department of Health and Social Care (UK)

Who is the main contact?
Prof Klaus Schmierer, assistms@qmul.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
336126

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 63752, Award ID: AI_AWARD02608

Study information

Scientific Title
Artificial intelligence-assisted magnetic resonance imaging for quality, efficiency and equity in the NHS care of multiple sclerosis - phase III: real world testing of icobrain ms

Acronym
AssistMS

Study objectives
To assess the clinical usefulness and cost-effectiveness of an Artificial Intelligence (AI) brain magnetic resonance imaging (MRI) quantification tool called icobrain ms, and to test its implementation in routine care at three clinical research sites.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 19/02/2025, London - Dulwich Research Ethics Committee (2 Redman Place - Stratford, London, E20 1JO, United Kingdom; +44 207 104 8290; dulwich.rec@hra.nhs.uk), ref: 24/PR/1584

Study design
Prospective individual randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
We will conduct a prospective clinical study to compare icobrain ms-assisted MRI to the current Standard of Care (SoC) in assessing disease activity. The Interventional arm is defined by ‘radiological reading by a neuro-radiologist assisted by icobrain ms. The SoC arm is defined by ‘radiological reading by a neuro-radiologist’. When describing SoC, the aim of the trial is not to provide a proscribed list of how a neuro-radiologist should read an MRI for this study, but to allow them to operate as they normally would.

The total duration of the intervention and follow-up for all study arms is 1 year. Participants will attend a clinic and MRI visit as per their standard of care where they will be screened for the study and if eligible and happy to take part in, they will be consented and randomised into the study. Randomisation will be performed by an authorised member of the research team at the site using a web-based randomisation service. In addition to this, participants will complete two questionnaires on their health-related quality of life and resource use. Both arms will be followed-up at 6 and 12 months after enrolment into the study. At 6 months, participants will complete two questionnaires on their health-related quality of life and resource use. At 12 months, participants will have a clinic and MRI visit as per their standard of care and complete two questionnaires on their health-related quality of life and resource use.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
icobrain ms

Primary outcome(s)
The proportion of patients have disease activity detected when icobrain ms is being employed, alongside the visual assessment, compared to SoC assessment by a (neuro)radiologist.

Key secondary outcome(s))

1. Brain volume loss based on baseline-year 1 and/or, where available, retrospective-baseline
2. Treatment initiation or switch decisions based on baseline-year 1 and/or, where available, retrospective-baseline
3. Number of relapse(s) measured using patient records from baseline to year 1
4. Clinical deterioration, stability or improvement measured using patient records based on baseline-year 1
5. Mean time (minutes/seconds) to produce a radiologist-authorised MRI brain report measured using patient records
6. Incremental cost per quality-adjusted life year (QALY) gained with use of icobrain ms measured using EQ-5D-5L and Resource Use questionnaires at baseline, 6 months and 12 months post-enrolment. The Resource Use Questionnaire is a purpose developed questionnaire asking participants to report their use of inpatient, outpatient and community healthcare, social care, help with personal care and out-of-pocket costs.

Completion date
15/04/2027

Eligibility

Key inclusion criteria
1. 18 years of age and above
2. Clinically Isolated Syndrome suggestive of demyelination (CIS) or definitive diagnosis of MS
3. Undergoing MRI head investigation
4. On an MS DMT pathway
5. Access to a smartphone, tablet or computer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
People with MS (pwMS) participating in a randomised controlled Clinical Trial of an investigational medicinal product (CTIMP) (pwMS participating in a single arm study may be included, provided this is acceptable with the CTIMP protocol)

Date of first enrolment

15/04/2025

Date of final enrolment
15/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
Department of Health and Social Care

Alternative Name(s)
Department of Health & Social Care, DH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes