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Spinal cord magnetic resonance imaging in multiple sclerosis

Submission date
15/01/2025

Recruitment status
Recruiting

Registration date
22/01/2025

Overall study status
Ongoing

Last Edited
18/09/2025

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 disease where inflammation causes damage to myelin and axons in nerves, in the brain and spinal cord, which ultimately leads to disability. How MS progresses over time differs greatly between individuals, and how severely someone will be affected is unpredictable. Measurements (or 'markers') of nerve damage are needed to help predict a person's future disease course and make better treatment decisions. Magnetic resonance imaging (MRI) can provide such markers. Volume measurements from standard MRI can determine nerve tissue shrinkage rates ('atrophy'), and specialised 'microstructural' MRI can provide more specific measures of the condition of axons and myelin in nerves. Although MS affects both the brain and spinal cord, nerve damage in MS has been mostly studied in the brain. Less is known about nerve damage in the spinal cord, although it is strongly linked to disability. Additionally, previous research has mainly focused on nerve damage in the upper part of the spinal cord and has not specifically explored cord damage in the early stages of MS. This pilot study (CORD-MS) aims to implement and test standard and specialised MRI methods along the full length of the spinal cord in a small group of people recently diagnosed with MS. This will provide crucial initial data and refine techniques to support a larger study on early-stage spinal cord nerve damage in MS. The ultimate goal is to support the development of better treatments for people with MS by 1) using standard MRI scans to create basic measurements of spinal cord volume, which can help doctors better understand and treat cord damage, and 2) using specialised MRI scans to measure cord health in more detail, which could lead to better treatments specifically focusing on nerve damage in MS.

Who can participate?
Adults over the age of 18 years old with a recent diagnosis (< 6 months) of relapsing-remitting MS.

What does the study involve?
Participants will be asked to join this study when they are at the Anne Rowling Regenerative Neurology Clinic. Study visits will take place at baseline and six months follow-up. At each time point, a participant will undergo a one-hour spinal cord MRI scan and approximately one hour of clinical disability assessments.

What are the possible benefits and risks of participating?
There is no immediate benefit for participants in this study. MRI biomarkers identified in this pilot study may, however, in the future, aid the development of treatments targeting neurodegeneration and remyelination in MS and thus benefit people living with MS. Further research is required before this can be realized. The main burden on participants will be the MRI examination. MRI is non-invasive, however, and does not involve ionising radiation; there is no known associated risk to the participant. Contrast agents will also not be used in this study.

Where is the study run from?
The Centre for Clinical Brain Sciences, University of Edinburgh, UK

When is the study starting and how long is it expected to run for?
May 2024 to April 2026

Who is funding the study?
The MS Society UK

Who is the main contact?
1. Dr Rozanna Meijboom, rozanna.meijboom@ed.ac.uk
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Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
346955

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
AC24219

Study information

Scientific Title
Quantitative spinal cord magnetic resonance imaging of demyelination and neurodegeneration in multiple sclerosis

Acronym
CORD-MS

Study objectives
Multiple sclerosis (MS) is a chronic neuroinflammatory and neurodegenerative disease of the brain and spinal cord that poses a significant health burden in the UK. Spinal cord progression occurs independently of brain changes and contributes disproportionately to a disability, however, it remains poorly understood. Clinical spinal cord magnetic resonance imaging (MRI) is currently limited to qualitative assessment of lesion burden. Accurate non-invasive in vivo MRI biomarkers specific for early-stage spinal cord demyelination and neurodegeneration are needed, however, quantitative structural and microstructural spinal cord MRI is technically challenging. This study aims to develop and optimise a dedicated quantitative structural and microstructural whole spinal cord MRI protocol for MS, allowing pathophysiological disease features to be measured in vivo across the disease course. This pilot study will provide critical proof of concept, feasibility and pilot data to support: 1. clinical translation of spinal cord atrophy measures, 2. further substantive mechanistic studies of spinal cord demyelination, neurodegeneration, and clinical trajectory in early MS. The ultimate aim is to translate precision spinal cord MRI metrics for improved clinical stratification and novel trial platforms for targeted remyelinating and neuroprotective therapies.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/06/2025, London - Camberwell St Giles Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048276; camberwellstgiles.rec@hra.nhs.uk), ref: 25/PR/0279

Study design
Single-centre longitudinal observational pilot study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Establishing spinal cord imaging biomarkers in people with recently diagnosed multiple sclerosis

Interventions
The pilot study will have two time points: baseline and 6-month follow-up. At each time point, a participant will undergo a 1-hour spinal cord MRI scan, including structural and advanced MRI sequences, and one hour of clinical disability assessments, including the Expanded-Disability Status Scale, Nine-Hole Peg Test and Timed 25-Foot Walk test.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Magnetic resonance imaging

Primary outcome(s)
Spinal cord atrophy, lesions and microstructure will be measured using spinal cord magnetic resonance imaging at baseline and 6-month follow-up

Key secondary outcome(s))
Physical disability will be measured using the Expanded-Disability Status Scale (EDSS), Nine-Hole Peg Test (9-HPT) and Timed 25-Foot Walk test (T25-FW) at baseline and 6-month follow-up

Completion date
01/05/2026

Eligibility

Key inclusion criteria
1. Recent diagnosis of relapsing-remitting multiple sclerosis (<6 months)
2. Aged 18 years or older
3. Capacity to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
1. Intake of disease-modifying treatments prescribed prior to baseline assessment
2. Participation in an interventional clinical trial prior to baseline assessment
3. Contraindications for MRI
4. Other neurological disorders
5. History of spinal injury

Date of first enrolment
13/10/2025

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Anne Rowling Regenerative Neurology Clinic
49 Little France Crescent
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Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Organisation
NHS Lothian

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society

Alternative Name(s)
mssocietyuk, MS Society UK, Multiple Sclerosis Society UK, Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made publicly available online due to privacy and confidentiality concerns.

IPD sharing plan summary
Not expected to be made available

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