ISRCTN99170029 https://doi.org/10.1186/ISRCTN99170029

Predictors of disease activity in multiple sclerosis

Submission date
10/07/2025

Recruitment status
Recruiting

Registration date
07/10/2025

Overall study status
Ongoing

Last Edited
13/11/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and aims
PrecisionMS is an observational study. Multiple sclerosis (MS) and MS-related neurological conditions can be unpredictable, with large variations in the rate of attacks (relapses) that patients experience. There are licensed treatments to reduce the relapse rate; however, choosing the right drug for the right person at the right time is challenging. More highly active drugs carry a higher risk of adverse effects, and the current standard approach is therefore for patients and doctors to react to what has happened in an individual's prior disease journey. This is not ideal as it allows potentially preventable relapses to occur, and may miss a narrow "window of opportunity" to control the disease early and gain better long-term results. There is a need for the ability to make personalised predictions of disease activity near diagnosis, allowing patients and doctors to plan care and make more informed, proactive choices about treatment. No drug will be given, delayed, or withheld as a result of participation. All the assessments take place as part of your routine clinical care. Researchers will analyse blood samples and brain scans, which are already being taken as part of your regular NHS review. Participants will be offered the opportunity to speak to a member of the study team after each of their routine clinic visits.

Who can participate?
Adults living with MS or MS-related neurological disorders within the NHS Lothian and NHS Highland health boards.

What does the study involve?
At the first baseline study visit, the research team will discuss the study, expectations, and requirements and will answer questions. Afterwards, if participants are willing, a consent form will be completed. This is followed by the collection of clinical information and a clinical examination. The study consists of a baseline visit and two follow-up visits at approximately one and two years after baseline. At the baseline visit, an optional 5-10 min questionnaire will be completed about their quality of life and preferences on how they would like to receive their research results. The research team will then collect routine NHS data. If data on height/weight /blood pressure measurements are missing, the team would like to perform those measurements during the visit. If participants do not have a routine blood test, the team will offer either a separate blood draw (1-2 tablespoons) on-site or a fingerprick test, which they can

do on-site or at home. All additional measurements are optional. After processing and analysing the data, results will be fed back to participants at their next routine appointment with the neurologist (approximately one year after their baseline visit), if they wish. This will be repeated once, i.e. data will be collected at the 1-year follow-up, processed and fed back at the next routine appointment with the neurologist (approximately two years after baseline). At the 1- and 2-year follow-up visits, they will be asked to complete a questionnaire to comment on their experience with this study design and have the opportunity to discuss results further with the research team. The feedback loop is optional.

What are the possible benefits and risks of participating?
There are no direct benefits anticipated as a result of participation in PrecisionMS. However, participants have the opportunity to receive their biomarker results, which may help them to understand more about their disease activity.

There are no substantial risks associated with taking part in PrecisionMS. Giving a blood sample is briefly uncomfortable and can occasionally result in local
bruising.

Where is the study run from?
1. The Anne Rowling Regenerative Neurology Clinic, Edinburgh, for NHS Lothian, UK.
2. The Clinical Research Facility, Inverness, for NHS Highland, UK.

When is the study starting and how long is it expected to run for?
August 2022 to June 2028

Who is funding the study?
1. The Chief Scientist Office Scotland (CSO), UK
2. The Anne Rowling Regenerative Neurology Clinic, Edinburgh, for NHS Lothian, UK

Who is the main contact?
Prof David Hunt (Honorary Consultant Neurologist and Professor of Neuroinflammatory Medicine), David.Hunt@ed.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof David Hunt

ORCID ID
https://orcid.org/0000-0003-4230-0207

Contact details
Anne Rowling Regenerative Neurology Clinic 49 Little France Crescent
EDINBURGH
United Kingdom
EH16 4SB
+44 (0)1314659517
David.Hunt@ed.ac.uk

Type(s)
Public

Contact name
Ms Judith Watt

Contact details
Anne Rowling Regenerative Neurology Clinic
Edinburgh
United Kingdom
EH16 4SB
+44 (0)1314659517
jwatt4@ed.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
322741

Protocol serial number
2023/0229, AC23105

Central Portfolio Management System (CPMS)
60366

Study information

Scientific Title
PrecisionMS: Clinical, laboratory, and neuroimaging predictors of disease activity in multiple sclerosis: an observational cohort study using datasets derived from routine care

Acronym
PrecisionMS

Study objectives
The main hypothesis of the study is that blood and imaging biomarkers, generated from routine standard of care investigations and datasets, can predict disease activity in a cohort of patients with recently diagnosed RRMS and a second cohort of patients with MS-related neurological disorders.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/11/2023, East Midlands - Derby Research Ethics Committee (2 Redman Place, Stratford, London, EC20 1JQ, United Kingdom; -; derby.rec@hra.nhs.uk), ref: 23/EM/0194

Study design
2-year prospective observational multi-centred observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Development of “disease activity” prediction tools based on next-generation biomarkers in people with multiple sclerosis to inform prospective decisions about the personalised risk /benefit relationship of available treatments

Interventions
Study visits will be fully integrated into routine clinical care with data collected from hospital electronic records on treatment, relapse frequency and the Expanded Disability Status Scale (EDSS), MRI data, quality of life and MS impact questionnaires. Research blood biomarkers are also collected.

Should patients request their biomarker data to be made available to them, they will be offered an additional 30 minutes with the study team to discuss the results after their routine clinic visit.

Intervention Type
Other

Primary outcome(s)
The development, validation and prediction of precision biomarkers for disease activity will be informed by measuring data collected from clinical, laboratory, and longitudinal neuroimaging assessments at the baseline visit, and 1- and 2-year follow-up visits

Key secondary outcome(s))
Secondary outcome measure data collection is undertaken at the baseline visit, and 1- and 2-year follow-up visits:
1. The difference in “precision biomarkers” between a real-world NHS setting and a research setting will be measured using comparative analysis at the time of biomarker assessment
2. The proportion of patients (MS of all subtypes and MS-related neurological diseases) who have disease activity identified using precision biomarkers that would not have otherwise been detected will be determined using retrospective review of clinical and biomarker data at the point of diagnosis or follow-up
3. Understanding of precision biomarker results by patients who request to see their results will be assessed using patient feedback or survey methods at the time results are shared

Completion date
01/06/2028

Eligibility

Key inclusion criteria
Cohort 1: Relapsing-remitting multiple sclerosis (RRMS)
1. Patients with RRMS fulfilling the 2017 McDonald criteria

2. Diagnosis of RRMS within 5 years of recruitment
3. Age ≥ 18 years
4. Capacity to provide informed consent

Cohort 2: Progressive MS and MS-related neurological disorders
1. Patients with MS fulfilling the 2017 McDonald criteria, including progressive MS at any stage
2. Diagnosis of RRMS outwith 5 years of recruitment
3. MS-related neurological disorders such as neuromyelitis optica spectrum disorder, clinically silent MS, chronic inflammatory demyelinating polyneuropathy and other neuroinflammatory or neurological disorders
4. Age ≥ 18 years
5. Capacity to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Age < 18 years at recruitment
2. Contraindication to MR brain imaging
3. Patient is outside NHS Lothian or NHS Highland

Date of first enrolment
02/08/2024

Date of final enrolment
01/06/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Anne Rowling Regenerative Neurology Clinic
Chancellor's Building
Edinburgh Bioquarter
49 Little France Crescent
Edinburgh
Scotland
EH16 4SB

Study participating centre
Inverness
Raigmore Hospital
Clinical Research Facility
UHI House (Formerly - Centre for Health Science)
Old Perth Road
Inverness
Scotland
IV2 3JH

Sponsor information

Organisation
NHS Lothian

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government

Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

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
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