

Predictors of disease activity in multiple sclerosis

Submission date 10/07/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/10/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/10/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

322741

ClinicalTrials.gov number

Nil Known

Secondary identifying numbers

2023/0229, AC23105

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

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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

Secondary study design

Cohort study

Study setting(s)

Home, Hospital, Laboratory, Medical and other records

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/08/2022

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

320

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

Scotland

United Kingdom

Study participating centre**Anne Rowling Regenerative Neurology Clinic**

Chancellor's Building

Edinburgh Bioquarter

49 Little France Crescent

Edinburgh

United Kingdom

EH16 4SB

Study participating centre**Inverness**

Raigmore Hospital

Clinical Research Facility

UHI House (Formerly - Centre for Health Science)

Old Perth Road

Inverness

United Kingdom

IV2 3JH

Sponsor information

Organisation

NHS Lothian

Sponsor details

ACCORD, Usher Building, The University of Edinburgh, 5-7 Little France Road

Edinburgh BioQuarter- Gate 3

Edinburgh

Scotland

United Kingdom

EH16 4UX

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enquiries@accord.scot

Sponsor type

Hospital/treatment centre

Website

<https://www.nhsllothian.scot/>

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

Local government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/08/2028

Individual participant data (IPD) sharing plan

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