ISRCTN82598726 https://doi.org/10.1186/ISRCTN82598726

MS-STAT2 : Multiple Sclerosis - Simvastatin Trial 2

Submission date 02/10/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/11/2017	**Overall study status** Completed	
Last Edited 16/12/2025	**Condition category** Nervous System Diseases	

Plain English summary of protocol

Background and study aims
Multiple Sclerosis (MS) is a progressive neurological disorder of the brain and spinal cord. It affects approximately 120,000 people in the UK and 2.5 million people globally. Most people with MS experience two stages of the disease: Early MS – Relapsing-Remitting MS (RRMS), which is partially reversible, and Late MS – Secondary Progressive MS (SPMS), which affects the majority of patients, usually after 10 to 15 years after diagnosis. SPMS results from progressive neuronal degeneration that causes accumulating and irreversible disability affecting walking, balance, manual function, vision, cognition, pain control, bladder and bowel function. The pathological process driving the accrual of disability in SPMS is not known at present. Immunomodulatory anti-inflammatory disease-modifying therapies (DMTs) are increasingly effective in reducing relapse frequency in RRMS, however, they have been unsuccessful in slowing disease progression in SPMS. This is the overwhelming conclusion from an analysis of 18 phase 3 trials (n=8500), of which 70% of the population had SPMS, all performed in the last 25 years. Siponimod was approved for use for SPMS in 2019 and is currently the only disease-modifying treatment (DMT) for SPMS. The aim of this study is to examine if repurposed Simvastatin (80mg) is a disease-modifying treatment for patients with progressing Secondary Progressive Multiple Sclerosis (SPMS).

Who can participate?
Adults aged 25 to 65 who have a confirmed diagnosis of MS.

What does the study involve?
The study is designed to test the effectiveness of repurposed simvastatin (80mg) in a phase 3 double blind, randomised, placebo controlled trial (1:1) in patients with secondary progressive MS (SPMS), to determine if the rate of disability progression can be slowed over a 3 year period. Participants will be required to complete a minimum of 10 study appointments over a 36-month period. This will involve nine (9) visits to the hospital for study appointments and at least one (1) telephone call. At each study visit, participants will be asked to complete a number of study assessments including questionnaires and provide blood samples. Participants who meet all entry requirements are randomly allocated to receive either Simvastatin or Placebo. Participants will start off taking one (40mg) Simvastatin/Placebo tablet once daily at night for 1 month. The dose will increase after this and participants will take two (80mg) Simvastatin/Placebo tablets

once daily at night for the next 35 months. Patients who have not had a confirmed disease progression event by 36 months will be invited to an optional series of additional 6-monthly visits to a maximum of 4.5 years from baseline (exact number dependent on duration until end of trial point).

What are the possible benefits and risks of participating?
The results generated from this trial may help to improve the treatment options of people with MS. In addition, taking part in this trial will mean regular review by an experienced neurologist regardless of the drug that participants are randomly allocated to receive. All medical procedures involve the risk of harm, but this is usually a low risk. In addition, there might be risks associated with this study that we do not yet know about.
Simvastatin is a well-tolerated drug and side effects are rare. However, in this trial, simvastatin will be given at a higher dose than is normally given to patients who use it to lower their cholesterol levels. Side effects can occasionally include muscle pain, tummy pain, blurred vision, dizziness and very rarely severe liver damage. Minor side effects include constipation, diarrhoea, fatigue and headaches. Participants are advised to inform their study doctor/nurse if they experience any of these side effects or have any concerns regarding their health at any point during the trial. Participants may be asked to attend the clinic for any additional visit(s) for further examination or tests.
There might be a risk of serious side effects when some medications are taken with the trial drug. Participants are advised to tell the study doctor about all medications they are taking before and during the trial. This includes other prescribed medicines, over the counter medicines, recreational drugs, herbal medicines or supplements. Grapefruit juice is known to interact unfavourably with simvastatin. Participants are advised not to drink grapefruit juice for the duration of the trial. The active study drug may pose unknown risks to a pregnant woman, an unborn baby, or a breastfeeding child. As such, pregnant women are not allowed to take part in this trial. Urine samples from female participants are tested at the screening visit (visit 1) to make sure they are not pregnant. All participants (male and female) are advised to use adequate contraception for the duration of the trial. All reasonable efforts are made to make this trial safe. Despite this, some risks might not be possible to predict.

Where is the study run from?
The study is being coordinated by the Comprehensive Clinical Trials Unit (UCL). Participants will have their study appointments at up to 30 participating Hospitals across the UK (England, Wales, Scotland, and Northern Ireland). The lead site is based at UCL (National Hospital for Neurology & Neurosurgery)

When is the study starting and how long is it expected to run for?
March 2017 to August 2024

Who is funding the study?
1. National Institute for Health Research (UK)
2. MS Society (UK)
3. National MS Society (USA)

Who is the main contact?
1. Mr James Blackstone
j.blackstone@ucl.ac.uk
2. Miss Rachel Merry
ms-stat2@ucl.ac.uk
3. Prof Jeremy Chataway
j.chataway@ucl.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Liz Deane

ORCID ID
https://orcid.org/0000-0002-1503-7768

Contact details
Comprehensive Clinical Trials Unit at UCL
Institute of Clinical Trials & Methodology
London
United Kingdom
WC1V 6LJ
+44 20 7907 4672
ms-stat2@ucl.ac.uk

Type(s)
Scientific

Contact name
Dr Jeremy Chataway

ORCID ID
https://orcid.org/0000-0001-7286-6901

Contact details
Institute of Neurology
University College London (UCL)
Queen Square
London
United Kingdom
WC1N 3BG
-
jeremy.chataway@uclh.nhs.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT03387670

Clinical Trials Information System (CTIS)
2017-003328-56

Integrated Research Application System (IRAS)
232288

Central Portfolio Management System (CPMS)
35831

Study information

Scientific Title
A phase 3 randomised, double blind, clinical trial investigating the effectiveness of repurposed simvastatin compared to placebo, in secondary progressive multiple sclerosis, in slowing the progression of disability

Acronym
MS-STAT2

Study objectives
The hypothesis is that repurposed Simvastatin (80 mg) is a disease modifying treatment for patients with progressing Secondary Progressive Multiple Sclerosis (SPMS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Westminster Research Ethics Committee, 09/10/2017, ref: 17/LO/1509

Primary study design
Interventional

Study design
Randomized; Interventional; Design type: Treatment, Drug

Study type(s)
Treatment

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

Interventions
Participants are randomly allocated to one of two groups:

Simvastatin (Active Treatment):
Participants in this group start off taking one tablet. The number of tablets increases to two after a month.
1. One (1 = 40 mg) simvastatin tablet once daily at night for one month
2. Two (2 = 80 mg) simvastatin tablets once daily at night, for the next 35 months*

Placebo:
Participants in this group start off taking one tablet. The number of tablets increases to two after a month.
1. One (1) placebo tablet once daily at night for one month
2. Two (2) placebo tablets once daily at night, for the next 35 months*

Participants are followed up on a six-month basis from baseline using the Expanded Disability Status Scale (EDSS) until the participant attends the last clinical appointment.

Added 15/11/2023:
*Extendable to up 54 months, for those participants taking part in the optional extension of IMP and follow-up, where they have not had confirmed disease progression by 36 months.

Intervention Type
Other

Primary outcome(s)
Time to initial disability progression between treatment arms is measured using the Expanded Disability Status Scale (EDSS) at baseline and then on a 6 month basis until last available EDSS score recorded at last attended clinic appointment/via telephone.

Key secondary outcome(s)
Current secondary outcome measures as of 15/11/2023:
Current secondary outcome measures:
1. The clinical effect of neuroprotection based on clinician- and patient-reported outcome measures
2. The incremental cost and cost-effectiveness of simvastatin versus standard care for the trial period and for the lifetime horizon

Clinician-reported outcome measures:
1. A modified Multiple Sclerosis Functional Composite (MSFC) outcome measure comprised of three components. The Symbol Digit Modalities Test (SDMT) will replace the Paced Auditory Serial Addition Test (PASAT), one of the three components in the standard MSFC.
1.1. Quantitative mobility and leg function measured using the 25-foot walk (T25FW) assessment at baseline, 6, 12, 18, 24, 30, 36 months and potentially at 42, 48 and 54 months for participants completing extension visits.
1.2. Fine motor coordination is measured using the 9 Hole peg test (9HPT) at baseline, 6, 12, 18, 24, 30, 36 months and potentially at 42, 48 and 54 months for participants completing extension visits.
1.3. Cognitive processing speed is measured using the Symbol digit modalities test (SDMT) at baseline, 12, 24 and 36 months.
2. Visual function is measured using the Sloan Low Contrast Visual Acuity (SLCVA) test at baseline, 12, 24 and 36 months.
3. Relapse assessment is measured by recording the number and severity experienced by participants at screening, baseline, 1, 3, 6, 12, 18, 24, 30, 36 months and potentially at 42, 48 and 54 months for participants completing extension visits.
4. The degree of disability in daily activities for patients with neurological disability is measured using the Modified Rankin Scale (mRS) at baseline, 12, 24 and 36 months.
5. Brief International Cognitive Assessment For Multiple Sclerosis (BICAMS), a composite cognitive assessment tool comprising of three components namely:
5.1. Cognitive processing speed is measured using the Symbol Digit Modalities Test (SDMT) at baseline, 12, 24 and 36 months.
5.2. Episodic verbal learning and memory measured using the California Verbal Learning Test-2 (CVLT-II) at baseline and 36 months.
5.3. Immediate visual learning is measured using the Brief Visuospatial Memory Test - Revised (BVMT-R) at baseline and 36 months.

Patient-reported outcome measures:
1. The impact of MS on people's lives is measured using the MS Impact Scale-29 v2 (MSIS-29v2) at baseline, 12, 24 and 36 months.
2. The impact of MS on the individual's walking ability is measured using the MS Walking Scale-12 v2 (MSWS-12v2) at baseline, 12, 24 and 36 months.
3. The impact of fatigue on cognitive, physical and psychosocial function in patients with MS is measured using the Modified Fatigue Impact Scale – 21 (MFIS-21) at baseline, 12, 24 and 36 months.
4. The severity of physical and mental fatigue is measured using the Chalder Fatigue Questionnaire (CFQ) at baseline, 12, 24 and 36 months.
5. Quality-adjusted life years (QALY) is measured using the EQ-5D 5L questionnaire at baseline, 6, 12, 18, 24, 30, 36 months.
6. Information on service utilisation, income, accommodation, and other cost-related variables is collected using the Client Services Receipt Inventory (CSRI) questionnaire at baseline, 6, 12, 18, 24, 30, 36 months.

Previous secondary outcome measures from 19/10/2018 to 15/11/2023:
1. The clinical effect of neuroprotection based on clinician- and patient-reported outcome measures
2. The incremental cost and cost-effectiveness of simvastatin versus standard care for the trial period and for the lifetime horizon

Clinician-reported outcome measures:
1. A modified Multiple Sclerosis Functional Composite (MSFC) outcome measure comprised of three components. The Symbol Digit Modalities Test (SDMT) will replace the Paced Auditory Serial Addition Test (PASAT), one of the three components in the standard MSFC.
1.1. 25 foot walk (T25FW)
1.2. 9 Hole peg test (9HPT)
1.3. Symbol digit modalities test (SDMT)
2. Sloan Low Contrast Visual Acuity (SLCVA)
3. Relapse assessment – number and severity
4. Frontal Assessment Battery (FAB)
5. Modified Rankin Scale (mRS)
6. Brief International Cognitive Assessment For Multiple Sclerosis (BICAMS), a composite cognitive assessment tool comprising of the three components namely:
6.1. Symbol Digit Modalities Test (SDMT)
6.2. California Verbal Learning Test-2(CVLT-2)
6.3. Brief Visuospatial Memory Test- Revised (BVMT-R)

Patient-reported outcome measures:
1. MS Impact Scale-29 v2 (MSIS-29v2)
2. MS Walking Scale-12 v2 (MSWS-12v2)
3. EQ-5D 5L

Previous secondary outcome measures:
1. The clinical effect of neuroprotection based on clinician and patient reported outcome measures
2. The incremental cost and cost-effectiveness of simvastatin versus standard care for the trial period and for the lifetime horizon

Clinician reported outcome measures:
1. A modified Multiple Sclerosis Functional Composite (MSFC) outcome measure comprised of

three components. The Symbol Digit Modalities Test (SDMT) will replace the Paced Auditory Serial Addition Test (PASAT), one of the three components in the standard MSFC.
1.1. 25 foot walk (T25FW)
1.2. 9 Hole peg test (9HPT)
1.3. Symbol digit modalities test (SDMT)
2. Sloan Low Contrast Visual Acuity (SLCVA)
3. Relapse assessment – number and severity
4. Frontal Assessment Battery (FAB)
5. Modified Rankin Scale (mRS)
6. Brief International Cognitive Assessment For Multiple Sclerosis (BICAMS), a composite cognitive assessment tool comprising of the three components namely:
6.1. Symbol Digit Modalities Test (SDMT)
6.2. California Verbal Learning Test-2(CVLT-2)
6.3. Brief Visuospatial Memory Test- Revised (BVMT-R)

Patient-reported outcome measures:
1. MS Impact Scale-29 v2 (MSIS-29v2)
2. MS Walking Scale-12 v2 (MSWS-12v2)
3. ABILHAND-56
4. EQ-5D 5L
5. SF-36 v2

Completion date
15/08/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 24/05/2020:
1. Patients with a confirmed diagnosis of multiple sclerosis (MS) that have entered the secondary progressive stage. Steady progression rather than relapse must be the major cause of increasing disability in the preceding 2 years. Progression can be evident from either an increase of at least 1 point if EDSS score <6, or an increase of 0.5 points if EDSS score ≥6, or clinical documentation of increasing disability
2. EDSS 4.0 - 6.5 (inclusive)
3. Aged 25 to 65 years old
4. Patients must be able and willing to comply with the terms of this protocol
5. Written informed consent provided

Previous participant inclusion criteria as of 19/10/2018:
1. Patients with a confirmed diagnosis of multiple sclerosis (MS) that have entered the secondary progressive stage. Steady progression rather than relapse must be the major cause of increasing disability in the preceding 2 years. Progression can be evident from either an increase of at least 1 point if on the Expanded Disability Status Scale (EDSS) score <6, or an increase of 0.5 point if EDSS score ≥6, or clinical documentation of increasing disability
2. EDSS 4.0 - 6.5 (inclusive)
3. Aged 25 to 65 years
4. Patients must be able and willing to comply with the terms of this protocol
5. Written informed consent provided

Previous participant inclusion criteria:
1. Patients with a confirmed diagnosis of multiple sclerosis (MS) that have entered the secondary progressive stage at randomisation. Steady progression rather than relapse must be the major cause of increasing disability in the preceding 2 years. Progression can be evident from either an increase of at least one point on the Expanded Disability Status Scale (EDSS), or clinical documentation of increasing disability
2. EDSS 4.0 - 6.5 (inclusive)
3. Aged 25 to 65 years old
4. Male or Female
5. Patients must be able and willing to comply with the terms of this protocol.
6. Written informed consent provided

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
25 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
964

Key exclusion criteria
Current participant exclusion criteria as of 15/11/2023:
Current participant exclusion criteria:
1. Relapse within 3 months of baseline visit. Patients will be eligible where 3 months from the final day of the relapse, has elapsed by the date of the baseline visit
2. Patients that have been treated with steroids (intravenous and/or oral) due to MS relapse /progression within 3 months from the final day of relapse to the baseline visit. These patients may undergo a further screening visit once the 3-month window has expired and may be included if no steroid treatment has been administered in the intervening period (Note: Patients on steroids for another medical condition may be included in the trial provided the steroid prescription is not for MS relapse/progression)
3. Significant organ co-morbidity e.g. cardiac failure, renal failure, malignancy
4. Screening levels of alanine aminotransferase (ALT) / aspartate aminotransferase (AST) or creatine kinase (CK) ≥3 x upper limit of normal (ULN)
5. Current use of a statin; or any use within the last 6 months
6. Medications that interact unfavourably with simvastatin as outlined in the current summary of product characteristics (SmPC); including but not limited to CYP3A4 inhibitors (e.g. itraconazole,

ketoconazole, posaconazole, voriconazole, fluconazole, HIV protease inhibitors (e.g. nelfinavir), boceprevir, erythromycin, clrithromycin, telithromycin, telaprevir, nefazodone, fibrates (including fenofibrates), nicotinic acid (or products containing niacin), azole anti-fungal preparations, macrolide antibiotics, protease inhibitors, verapamil, amiodarone, amlodipine, gemfibrozil, ciclosporin, danazol, diltiazem, rifampicin, fusidic acid, elbasvir, grazoprevir, ticagrelor, daptomycin, grapefruit juice or alcohol abuse;
7. Primary progressive MS
8. Diabetes mellitus type 1
9. Uncontrolled hypothyroidism
10. Female participants who are pregnant or breastfeeding. Women of childbearing potential (WOCBP) who are unwilling or unable to use an acceptable method to avoid pregnancy for the entire study period, and up to 4 weeks after the last dose of study drug
11. Use of immunosuppressants (e.g. azathioprine, methotrexate, ciclosporine) or disease-modifying treatments (avonex, rebif, betaferon, glatiramer) within the previous 6 months
12. Use of mitoxantrone, natalizumab, alemtuzumab, daclizumab or other monoclonal antibody treatment, if treated within the last 12 months;
13. Use of fingolimod, dimethyl fumarate, teriflunomide, cladribine within the last 12 months
14. Use of other experimental disease-modifying treatment within the last 6 months
15. Commencement of fampridine ≤6 months from the day of randomisation
16. Concurrent participation in another clinical trial of an investigational medicinal product or medical device
17. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption

Previous participant exclusion criteria from 24/05/2020 to 15/11/2023:
1. Relapse within 3 months of baseline visit
2. Patients that have been treated with steroids (intravenous and/or oral) due to MS relapse /progression within 3 months of baseline visit. These patients may undergo a further screening visit once the 3-month window has expired and may be included if no steroid treatment has been administered in the intervening period. Patients on steroids for another medical condition may be included in the trial provided.
the steroid prescription is not for MS relapse/progression)
3. Significant organ co-morbidity e.g. cardiac failure, renal failure, malignancy
4. Screening levels of alanine aminotransferase (ALT) / aspartate aminotransferase (AST) or creatine kinase (CK) ≥3 x upper limit of normal (ULN)
5. Current use of a statin; or any use within the last 6 months
6. Medications that interact unfavourably with simvastatin as outlined in the current summary of product characteristics (SmPC); including but not limited to CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, posaconazole, voriconazole, fluconazole, HIV protease inhibitors (e. g. nelfinavir), boceprevir, erythromycin, clarithromycin, telithromycin, telaprevir, nefazodone, fibrates (including fenofibrates), nicotinic acid (or products containing niacin), azole anti-fungal preparations, macrolide antibiotics, protease inhibitors, verapamil, amiodarone, amlodipine, gemfibrozil, ciclosporin, danazol, diltiazem, rifampicin, fusidic acid, elbasvir, grazoprevir, grapefruit juice, or alcohol abuse
7. Primary progressive MS
8. Diabetes mellitus type 1
9. Uncontrolled hypothyroidism
10. Female participants who are pregnant or breastfeeding. Women of childbearing potential (WOCBP) who are unwilling or unable to use an acceptable method to avoid pregnancy for the entire study period, and up to 4 weeks after the last dose of study drug
11. Use of immunosuppressants (e.g. azathioprine, methotrexate, ciclosporine) or disease-modifying treatments (avonex, rebif, betaferon, or glatiramer) within the previous 6 months

12. Use of mitoxantrone, natalizumab, alemtuzumab, daclizumab or other monoclonal antibody treatment, if treated within the last 12 months
13. Use of fingolimod, dimethyl fumarate, teriflunomide, cladribine within the last 12 months
14. Use of other experimental disease-modifying treatment within the last 6 months
15. Commencement of fampridine ≤6 months from the day of randomisation
16. Concurrent participation in another clinical trial of an investigational medicinal product or medical device
17. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption

Previous participant exclusion criteria as of 19/10/2018:
1. Relapse within 3 months of baseline visit
2. Patients that have been treated with steroids (intravenous and/or oral) due to MS relapse /progression within 3 months of baseline visit. These patients may undergo a further screening visit once the 3-month window has expired and may be included if no steroid treatment has been administered in the intervening period (Note: Patients on steroids for another medical condition may be included in the trial provided the steroid prescription is not for MS relapse /progression)
3. Significant organ co-morbidity e.g. cardiac failure, renal failure, malignancy
4. Screening levels of alanine aminotransferase (ALT) / aspartate aminotransferase (AST) or creatinine kinase (CK) > = 3x upper limit of normal (ULN)
5. Current use of a statin; or any use within the last 6 months
6. Medications that interact unfavourably with simvastatin as outlined in the current summary of product characteristics (SmPC); including but not limited to CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, posaconazole, voriconazole, fluconazole, HIV protease inhibitors (e.g. nelfinavir), boceprevir, erythromycin, clarithromycin, telithromycin, telaprevir, nefazodone, fibrates (including fenofibrates), nicotinic acid (or products containing niacin), azole anti-fungal preparations, macrolide antibiotics, protease inhibitors, verapamil, amiodarone, amlodipine, gemfibrozil, ciclosporin, danazol, diltiazem, rifampicin, fusidic acid, grapefruit juice or alcohol abuse
7. Primary progressive MS
8. Diabetes Mellitus Type 1
9. Uncontrolled hypothyroidism
10. Female participants who are pregnant or breastfeeding. Women of childbearing potential (WOCBP) who are unwilling or unable to use an acceptable method to avoid pregnancy for the entire study period, and up to 4 weeks after the last dose of the study drug
11. Use of immunosuppressants (e.g. azathioprine, methotrexate, ciclosporine) or disease-modifying treatments (avonex, rebif, betaferon, glatiramer) within the previous 6 months
12. Use of mitoxantrone, natalizumab, alemtuzumab, daclizumab or other monoclonal antibody treatment, if treated within the last 12 months
13. Use of fingolimod, fumarate, teriflunomide within the last 12 months
14. Use of other experimental disease-modifying treatment within the last 6 months
15. Commencement of Fampridine <=6 month from day of randomisation
16. Concurrent participation in another clinical trial of an investigational medicinal product or medical device
17. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption

Previous participant exclusion criteria:
1. Relapse within 3 months of baseline visit
2. Patients that have been treated with steroids (intravenous and/or oral) due to MS relapse /progression within 3 months of baseline visit. These patients may undergo a further screening

visit once the 3-month window has expired and may be included if no steroid treatment has been administered in the intervening period (Note: Patients on steroids for another medical condition may be included in the trial provided the steroid prescription is not for MS relapse /progression)
3. Significant organ co-morbidity e.g. cardiac failure, renal failure, malignancy
4. Screening levels of alanine aminotransferase (ALT) / aspartate aminotransferase (AST) or creatinine kinase (CK) > = 3x upper limit of normal (ULN)
5. Current use of a statin; or any use within the last 6 months
6. Medications that interact unfavourably with simvastatin as outlined in the current summary of product characteristics (SmPC); including but not limited to CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, posaconazole, voriconazole, fluconazole, HIV protease inhibitors (e.g. nelfinavir), boceprevir, erythromycin, clarithromycin, telithromycin, telaprevir, nefazodone, fibrates (including fenofibrates), nicotinic acid (or products containing niacin), azole anti-fungal preparations, macrolide antibiotics, protease inhibitors, verapamil, amiodarone, amlodipine, gemfibrozil, ciclosporin, danazol , diltiazem, rifampicin , fusidic acid, grapefruit juice or alcohol abuse
7. Primary progressive MS
8. Diabetes Mellitus Type 1
9. Uncontrolled hypothyroidism
10. Female participants who are pregnant or breastfeeding. Women of childbearing potential (WOCBP) who are unwilling or unable to use an acceptable method to avoid pregnancy for the entire study period, and up to 4 weeks after the last dose of study drug
11. Use of immunosuppressants (e.g. azathioprine, methotrexate, ciclosporine) or disease-modifying treatments (avonex, rebif, betaferon, glatiramer) within the previous 6 months
12. Use of mitoxantrone, natalizumab, alemtuzumab, daclizumab or other monoclonal antibody treatment, if treated within the last 12 months
13. Use of fingolimod, fumarate, teriflunomide within the last 12 months
14. Use of other experimental disease-modifying treatment within the last 6 months
15. Commencement of Fampridine <=6 month from day of randomisation
16. Concurrent participation in another clinical trial of an investigational medicinal product or medical device

Date of first enrolment
28/03/2018

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UCL - National Hospital for Neurology & Neurosurgery
Queen Square
London

England
WC1N 3BG

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

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

Funder Name
MS Society UK

Funder Name
National MS Society (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2025	06/10/2025	Yes	No
Protocol article		16/09/2024	17/09/2024	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 2.0	01/07/2024	08/12/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes