ISRCTN14048364 https://doi.org/10.1186/ISRCTN14048364

Testing and comparing multiple drugs at once against the standard treatment for progressive multiple sclerosis treatment

Submission date
10/08/2022

Recruitment status
Recruiting

Registration date
25/10/2022

Overall study status
Ongoing

Last Edited
06/05/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] 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) affects more than 130,000 people in the UK and over 2.5 million people worldwide. MS often begins with a relapsing-remitting phase (RRMS). However, over time, many people with RRMS start to find that they no longer recover after a flare-up (also known as a relapse) and get steadily worse, resulting in increased disability. This is known as secondary progressive MS (SPMS). A smaller number of people experience a gradual decline from the beginning, known as primary progressive MS (PPMS). SPMS and PPMS together are known as progressive MS.
Recently, the first treatments have become available through the NHS for people with progressive MS. However, these treatments are only available to those who have had a relapse or have shown activity on an MRI scan. There are few clinical trials testing for effective treatments in progressive MS even though it is a major unmet need.
The main aim of OCTOPUS is to find treatments that can slow down, and ultimately stop, the progression of disability in people with progressive MS. This will be done by testing "repurposed" treatments (i.e. treatments already in use for other conditions), over several years, using the multi-arm multi-stage (MAMS) trial design.
This method has many advantages over traditional trials. Firstly, it allows several treatments to be tested at the same time against a common control (i.e. "multi-arm"). Secondly, it allows data to be analysed while the trial is ongoing, rather than only at the end. This means that decisions can be made on early results about stopping treatments that do not show promise. Thirdly, when new information about different treatments becomes available, these treatments can be added into the trial. Finally, treatments which appear to be effective from the early data can continue onto the next trial phase without the team having to stop and set up a new trial (i.e. "multi-stage").
Using repurposed treatments means there is already an understanding of their safety and possible side effects and it will take less time to test them for progressive MS. By using this approach and adding new treatment arms when promising treatments are found, we can find effective new treatments for progressive MS quicker.

Who can participate?
Adults with progressive MS who are between 25 and 70 years of age and meet the trial's eligibility criteria.

What does the study involve?
The trial compares “repurposed” treatment groups against a control (often referred to as a placebo) group. People eligible to join OCTOPUS treatments will be randomly assigned (by a computer programme) to one of the groups, also known as ‘arms’. To ensure a fair and unbiased trial neither the research team nor the participant will know which treatment they are taking. All groups will receive the current standard of care for people with progressive MS (i.e. the same care they would receive if they were not part of OCTOPUS) plus the treatment they have been randomly allocated to (i.e. control (placebo) or a “repurposed” treatment group).
Disability will be measured in different ways, including testing strength, coordination and sensation, walking assessments and tests of upper limb function. Results will be measured at the trial visits. Optional blood samples may be taken, with participants’ permission. The visits will at first be monthly and then six monthly.
An early sign of the potential effectiveness of a treatment is a change in brain size. To measure changes in brain size, participants will undergo brain MRIs in Stage 1 of the study (four scans). Based on these scans, a decision will be made by an independent Trial Steering Committee on whether a treatment should be stopped or continued. Participants who are in an arm that is stopped will be offered the opportunity to be re-randomised into a different arm, after a wash-out period.
Other assessments, done every six months will include tests of memory, vision; and questionnaires about symptoms of MS including fatigue, mobility, and quality of life. Blood tests will also be performed to check the safety of the treatments. New clinical trial processes may allow some of these assessments to be done at home, e.g. the questionnaires.

What are the possible benefits and risks of participating?
It is hoped that the treatments will help people with progressive MS by slowing down, and ultimately stopping, the progression of disability; however, this is not known for sure, which is why it is being tested in this trial.
It is possible that the results may not help people with progressive MS who join the trial individually but the information from this trial will help improve treatment for people with Progressive MS in the future. Risks of participating include those of extra visits to hospital, MRI scans, and blood tests. Participants may also experience different or extra side effects. The most common unwanted side effects will be described in all information provided to potential participants.
The risks in pregnancy are unclear, therefore, participants will be asked to use contraceptives whilst on the trial.

Where is the study run from?
The study is run by Neurology trial centres around the UK and Australia, is sponsored by UCL and is managed by the MRC Clinical Trials Unit at UCL. Griffith University is the National Sponsor in Australia. Note that in Australia the trial is known as “PLATYPUS, the Australian extension of OCTOPUS”.

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

Who is funding the study?
MS Society (UK) with supportive funding from MS Australia and MS Western Australia to cover Australian operations.

Who is the main contact?
mrcctu.octopus@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Cheryl Pugh

Contact details
2nd Floor
90 High Holborn
London
United Kingdom
WC1V 6LJ
+44 (0)207 670 4700
mrcctu.octopus@ucl.ac.uk

Type(s)
Principal investigator

Contact name
Prof Jeremy Chataway

Contact details
235 Euston Road
London
United Kingdom
WC1N 3BG
+44 (0)203 108 1955
j.chataway@ucl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2021-003034-37

Integrated Research Application System (IRAS)
1003943

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ND001, IRAS 1003943, CPMS 54274

Study information

Scientific Title
OCTOPUS - Optimal Clinical Trials Platform for Progressive Multiple Sclerosis

Acronym
OCTOPUS (PLATYPUS in Australia)

Study objectives
The main aim of OCTOPUS is to find treatments that can slow down, and ultimately stop, the progression of disability in people with progressive MS. This will be done initially by testing “repurposed” treatments over a number of years using the multi-arm multi-stage (MAMS) trial design. By using this approach with new research treatments added when appropriate and by using “repurposed” treatments, it aims to be a more efficient trial.

Secondary objectives of OCTOPUS are: to determine the safety and tolerability of the researched treatments for people with progressive MS when taken over a number of years; to determine the effects of the treatments on quality of life and patient reported outcomes in people with progressive MS; and to determine the cost effectiveness of the treatments for people with progressive MS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/10/2022, London - Hampstead Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8345; hampstead.rec@hra.nhs.uk), ref: 22/LO/0622

Study design
Interventional double-blind randomized multi-arm multi-stage trial design (MAMS) placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Primary progressive multiple sclerosis and secondary progressive multiple sclerosis

Interventions
Participants will be randomised at each site via the OCTOPUS eDC System, a centrally managed system hosted by MRC CTU, accessible to authorised members of the research teams at recruiting site using a web-based interface. Eligibility and consent will be verified before each participant is randomised and is then confirmed within the system at the time of randomisation. If participants are ineligible for an arm, they can be assessed for eligibility and randomised to other open arms. Participants will be allocated using an eDC system into one of the three arms in a 1:1:1 ratio utilising minimisation based on key prognostic factors and a random element.

OCTOPUS is a blinded trial therefore all participants have the same dosing and assessment schedule. Following randomisation, participants will initially be asked to take the “low dose” of 2 capsules a day in the evening shortly after a meal (called the low dose) for 4 weeks. If the participant is tolerating this dose and they are happy to do so, they will then have their dosage increased to the high dose of 2 capsules twice a day shortly after meals (a total of 4 capsules). Participants will be asked to visit your study doctor at one month; have a telephone call at three months, and then another visit at six months. After this you will be asked to visit the hospital every 6 months for up to 5 years. Between the 6 monthly visits you will be asked to do a urine test and have a telephone call with the research nurse to report the result. At each visit to the hospital, participants will have the physical assessments to test the neurological system, and fill in questionnaires on pain, fatigue, mobility, and quality of life. Further tests will be done to check their progress and if they have any problems with the treatment. Depending on side effects and tolerability dose may be modified accordingly in accordance with the protocol.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Redacted drug A, redacted drug B

Primary outcome(s)
Primary Outcome for Analysis stage 1: Whole brain atrophy rate, as measured by the SIENA technique at baseline, 26, 78, and 104 weeks (i.e. baseline, 6, 18 and 24 months).

Primary Outcome for Analysis stage 2: Time to initial disability progression, which must be confirmed 6 months later i.e. Confirmed Disability Progression (CPE). It is measured by multicomponent measure of sustained disability progression comprising the Expanded Disability Status Scale (EDSS), timed 25-foot walk (T25FW) and 9-hole peg test (9HPT). These are carried out 6-monthly from baseline until last available score recorded at last attended clinic appointment.

Progression of disability is defined by progression on at least one of the three parameters:
1. EDSS – an increase of at least 1 point if EDSS score at baseline (randomisation) visit is <5.5, or an increase of 0.5 point if EDSS score at baseline (randomisation) is ≥5.5.
2. Increase of 20% or more from baseline on the T25FW.
3. Increase of 20% or more from baseline (on either hand) on the 9HPT.

Key secondary outcome(s))
Secondary outcome measures for analysis stage 1:
A. MRI outcome measures
1. Regional atrophy
2. Cervical cord atrophy
3. T2 lesion quantification, measured at baseline, 26, 78, and 104 weeks (i.e. baseline, 6, 18 and 24 months)
B. Clinician reported outcome measures. All measured at baseline and six monthly until 5 years or primary analysis, whichever comes first
1. Time to initial disability progression

2. Expanded Disability Status Scale (EDSS)
3. Timed 25-Foot Walk (T25FW)
4. 9 Hole Peg Test (9HPT)
5. Symbol Digit Modalities Test (SDMT)
6. MS Functional Composite Z score (comprising of T25FW, 9HPT, SDMT)
7. Sloan Low contrast visual acuity (SLCVA)
8. Relapse rate
C. Patient-reported outcome measures. All measured at baseline and six monthly until 5 years or primary analysis, whichever comes first
1. Multiple Sclerosis Impact Scale v2 (MSIS29v2)
2. Multiple Sclerosis Walking Scale v2 (MSWSv2)
3. Fatigue (MFIS-21 and CFQ)
4. Pain assessment (Neuropathic Pain Scale and Numerical Pain Rating Score)

Secondary outcome measures for analysis stage 2:
All measured at baseline and every 26 weeks (6 monthly) until 5 years
A. Clinician reported outcome measures
1. Time to initial disability progression
2. Expanded Disability Status Scale (EDSS)
3. Timed 25-Foot Walk (T25FW)
4. 9 Hole Peg Test (9HPT)
5. Symbol Digit Modalities Test (SDMT)
6. MS Functional Composite Z score (comprising of T25FW, 9HPT, SDMT)
7. Sloan Low contrast visual acuity (SLCVA)
8. Relapse rate
B. Patient-reported outcome measures
1. Multiple Sclerosis Impact Scale v2 (MSIS29v2)
2. Multiple Sclerosis Walking Scale v2 (MSWSv2)
3. Fatigue (MFIS-21 and CFQ)
4. Pain assessment (Neuropathic Pain Scale and Numerical Pain Rating Score)
C. Health-related quality of life and resource use
1. EQ 5D 5L Health Questionnaire
2. Client Services Receipt Inventory (CSRI)

Completion date
31/12/2028

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/05/2025:

Core Inclusion Criteria:
1. Participants with a confirmed diagnosis of MS
2. A diagnosis of Secondary Progressive MS (SPMS) or Primary Progressive MS (PPMS)
3. Steady progression as assessed by the treating clinician, 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 <5.5, or an increase of at least 0.5 point if EDSS score ≥5.5, and/or clinical documentation of increasing disability
4. EDSS 4.0 – 8.0 (inclusive) as assessed at the time of randomisation by the assessing clinician

5. Aged 25 - 70 years old inclusive on the day of randomisation
6. Adequate renal function at screening, defined as eGFR ≥60ml/min/1.73m² (as per local method)
7. Normal liver function at screening consisting of all the following:
7.1. Serum bilirubin <1.5 x ULN (except for participants with Gilbert's disease, for whom the upper limit of serum bilirubin is 51.3 µmol/l or 3mg/dl)
7.2. Either aspartate aminotransferase (AST) or alanine aminotransferase (ALT) <3 x ULN; (it must be stated whether one or both tests were performed. Where both results are available, both must confirm eligibility)
7.3. Alkaline phosphastase <3 x ULN
8. Must be able and willing to comply with the treatment and assessment schedule and requirements including being able to start trial treatment ≤ 2 weeks after randomisation.
9. Written informed consent provided
10. [Please note no longer core inclusion criteria in Analysis Stage 2 - Must have a QC approved (as defined in MRI guide) MRI ≤ 4 weeks before randomisation]
11. [Please note no longer core inclusion criteria in Analysis Stage 2 - Willing and able to have MRI scans in accordance with the assessment schedule and no contraindication to MRI (please refer to MRI Procedures and Protocol for further detail)]

Redacted drug B Inclusion Criteria:
Participants will be considered eligible for randomisation in this trial if they fulfil all the core inclusion criteria and none of the exclusion criteria as defined in sections 3.1 and 3.2 in the main protocol in addition to the arm specific criteria below. If a participant is ineligible for this arm, they can be assessed for eligibility and randomised to other open arms.

Redacted drug A Inclusion Criteria:
Participants will be considered eligible for randomisation in this trial if they fulfil all the core inclusion criteria and none of the exclusion criteria as defined in sections 3.1 and 3.2 in the main protocol in addition to the arm specific criteria below. If a participant is ineligible for this arm, they can be assessed for eligibility and randomised to other open arms.

———

Previous inclusion criteria as of 16/10/2024:

Core Inclusion Criteria:
1. Participants with a confirmed diagnosis of MS
2. A diagnosis of Secondary Progressive MS (SPMS) or Primary Progressive MS (PPMS)
3. Steady progression as assessed by the treating clinician, 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 <5.5, or an increase of at least 0.5 point if EDSS score ≥5.5, and/or clinical documentation of increasing disability
4. EDSS 4.0 – 8.0 (inclusive) as assessed at the time of randomisation by the assessing clinician
5. Aged 25 - 70 years old inclusive on the day of randomisation
6. Adequate renal function at screening, defined as eGFR ≥60ml/min/1.73m² (as per local method)
7. Normal liver function at screening consisting of all the following:
7.1. Serum bilirubin <1.5 x ULN (except for participants with Gilbert's disease, for whom the upper limit of serum bilirubin is 51.3 µmol/l or 3mg/dl)
7.2. Either aspartate aminotransferase (AST) or alanine aminotransferase (ALT) <3 x ULN; (it must be stated whether one or both tests were performed. Where both results are available,

both must confirm eligibility)
7.3. Alkaline phosphastase <3 x ULN
8. Must be able and willing to comply with the treatment and assessment schedule and requirements including being able to start trial treatment ≤ 2 weeks after randomisation.
9. Written informed consent provided
10. Must have a QC-approved (as defined in MRI guide) MRI ≤ 4 weeks before randomisation (Stage 1 of study ONLY)
11. Willing and able to have MRI scans in accordance with the assessment schedule and no contraindication to MRI (Stage 1 of study ONLY) please refer to MRI Procedures and Protocol for further detail.

Redacted drug B Inclusion Criteria:
Participants will be considered eligible for randomisation in this trial if they fulfil all the core inclusion criteria and none of the exclusion criteria as defined in sections 3.1 and 3.2 in the main protocol in addition to the arm specific criteria below. If a participant is ineligible for this arm, they can be assessed for eligibility and randomised to other open arms.

Redacted drug A Inclusion Criteria:
Participants will be considered eligible for randomisation in this trial if they fulfil all the core inclusion criteria and none of the exclusion criteria as defined in sections 3.1 and 3.2 in the main protocol in addition to the arm specific criteria below. If a participant is ineligible for this arm, they can be assessed for eligibility and randomised to other open arms.

———

Previous inclusion criteria:

Core Inclusion Criteria:
1. Participants with a confirmed diagnosis of MS
2. A diagnosis of Secondary Progressive MS (SPMS) or Primary Progressive MS (PPMS)
3. Steady progression as assessed by the treating clinician, 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 <5.5, or an increase of at least 0.5 point if EDSS score ≥5.5, and/or clinical documentation of increasing disability
4. EDSS 4.0 – 8.0 (inclusive) as assessed at the time of randomisation by the assessing clinician
5. Aged 25 - 70 years old inclusive on the day of randomisation
6. Adequate renal function at screening, defined as eGFR ≥60ml/min/1.73m² (as per local method)
7. Normal liver function at screening consisting of all the following:
7.1. Serum bilirubin <1.5 x ULN (except for participants with Gilbert's disease, for whom the upper limit of serum bilirubin is 51.3 µmol/l or 3mg/dl)
7.2. Either aspartate aminotransferase (AST) or alanine aminotransferase (ALT) <3 x ULN; (it must be stated whether one or both tests were performed. Where both results are available, both must confirm eligibility)
7.3. Alkaline phosphastase <3 x ULN
8. Must be able and willing to comply with the treatment and assessment schedule and requirements including being able to start trial treatment ≤ 2 weeks after randomisation.
9. Written informed consent provided
10. Must have a QC-approved (as defined in MRI guide) MRI ≤ 4 weeks before randomisation
11. Willing and able to have MRI scans in accordance with the assessment schedule and no contraindication to MRI (please refer to MRI Procedures and Protocol for further detail)

Redacted drug B Inclusion Criteria:
Participants will be considered eligible for randomisation in this trial if they fulfil all the core inclusion criteria and none of the exclusion criteria as defined in sections 3.1 and 3.2 in the main protocol in addition to the arm specific criteria below. If a participant is ineligible for this arm, they can be assessed for eligibility and randomised to other open arms.

Redacted drug A Inclusion Criteria:
Participants will be considered eligible for randomisation in this trial if they fulfil all the core inclusion criteria and none of the exclusion criteria as defined in sections 3.1 and 3.2 in the main protocol in addition to the arm specific criteria below. If a participant is ineligible for this arm, they can be assessed for eligibility and randomised to other open arms.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
1. Relapse ≤ 12 weeks before randomisation
2. Significant comorbidity (as confirmed by treating clinician)
2.1. Cardiac failure (clinical diagnosis)
2.2. Significant Respiratory comorbidity
2.3. Renal failure
2.4. Malignancy (except if in complete remission) – e.g. solid organ or haematological or melanoma
2.5. Uncontrolled thyroid disease
3. Rare hereditary problems of galactose intolerance or glucose-galactose malabsorption
4. Active partial or total malabsorptive disease (e.g. coeliac disease)
5. Has a history of alcohol use disorder and/or drug abuse (excluding cannabis for symptomatic relief)
6. Female participants that are pregnant or breast-feeding.
7. Women of child-bearing potential (WOCBP) who are unwilling or unable to use an acceptable method of contraception whilst on trial treatment and up to 12 weeks after the last dose of study drug.
8. Participation in another clinical trial of an investigational medicinal product or medical device ≤ 26 weeks before randomisation
9. Men with a partner of child-bearing potential unwilling to use an acceptable method of

contraception during the trial and for 12 weeks after the last dose of trial treatment.
10. Male participants unwilling to desist from sperm donation during the trial and for 12 weeks after the last dose of trial treatment.
11. Been treated with steroids (intravenous and/or oral) for MS relapse or progression ≤ 12 weeks before randomisation*
Note: Participants on steroids for another medical condition may be included in the trial provided the steroid prescription is not for any aspects of their MS.
12. Current or previous treatment with Analysis Stage 1 IMPs ≤ 26 weeks before randomisation. With the exception of participants taking [redacted drug name and dosage]. These participants can be randomised but must wait 7 days from the last dose before randomisation.
13. Commencement of DMT and/or fampridine ≤ 26 weeks before randomisation*
14. Contraindicated medications that are not permitted with OCTOPUS IMPs. Please note a careful approach should be applied to those listed with caution. Please contact the OCTOPUS team if further advice is required.
15. Participants who are not eligible for any of the trial IMPs, according to the eligibility criteria listed in the individual drug appendices. Please note that participants can enter the trial if they are eligible for at least one of the trial treatment arms, but do not need to be eligible for all.
*These participants may undergo a further screening visit once the specified window has expired and may be included if no further treatment has been administered in the intervening period.

Redacted drug B Exclusion Criteria:
Arm-specific exclusion criteria to be added when drug names released

Redacted drug A Exclusion Criteria:
Arm-specific exclusion criteria to be added when drug names released

Date of first enrolment
18/01/2023

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Australia

Study participating centre

Belfast City Hospital
51 Lisburn Rd
Belfast
United Kingdom
BT9 7AB

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
The Anne Rowling Regenerative Neurology Clinic
Chancellors Building
49 Little France Crescent
Edinburgh
United Kingdom
EH16 4SB

Study participating centre
Leeds General Infimary
Great George Street
Leeds

United Kingdom
LS1 3EX

Study participating centre
Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
United Kingdom
S10 2JF

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Cwmrhydyceirw
Swansea
United Kingdom
SA6 6NL

Study participating centre
National Hospital for Neurology & Neurosurgery - Queen Square
Queen Square
London
United Kingdom
WC1N 3BG

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Organisation
Griffith University

ROR
https://ror.org/02sc3r913

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

Funder Name
Multiple Sclerosis Australia

Funder Name
Multiple Sclerosis Western Australia

Results and Publications

Individual participant data (IPD) sharing plan
Applications for access to data can be made as following each analysis such as Analysis Stage 1 analysis for arms that do not continue. Researchers wishing to access OCTOPUS data should contact the Trial Management Group which will act as the “Data Re-Use Committee” in the first instance. Data will be shared based on the following principles:
No data should be released that would compromise an ongoing trial or study.
There must be a strong scientific or other legitimate rationale for the data to be used for the requested purpose.
Investigators who have invested time and effort into developing a trial or study should have a period of exclusivity in which to pursue their aims with the data, before key trial data are made available to other researchers.
The resources required to process requests should not be under-estimated, particularly successful requests, which lead to preparing data for release. Therefore, adequate resources must be available in order to comply in a timely manner or at all, and the scientific aims of the study must justify the use of such resources.
Data exchange complies with Information Governance and Data Security Policies in all of the relevant countries.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 4.0	28/04/2023	26/09/2023	No	Yes
Participant information sheet	MRI setup version 3.0	28/04/2023	26/09/2023	No	Yes
Participant information sheet	Pregnancy information sheet version 3.0	28/04/2023	26/09/2023	No	Yes
Participant information sheet	Visit information leaflet version 3.0	28/04/2023	26/09/2023	No	Yes
Participant information sheet	version 5.0	14/03/2024	09/10/2024	No	Yes
Participant information sheet	version 6.0	30/09/2024	02/05/2025	No	Yes
Protocol file	version 3.0	28/04/2023	26/09/2023	No	No
Protocol file	version 6.0	29/07/2024	09/10/2024	No	No
Protocol file	version 7.0	30/09/2024	02/05/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes