ISRCTN50440735 https://doi.org/10.1186/ISRCTN50440735

Phase I Trial: Sponsor code: X11-201-00001

Submission date 28/03/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 31/03/2025	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 31/03/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1009721

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Sponsor code: X11-201-00001

Study information

Scientific Title
Phase I Trial: Sponsor code: X11-201-00001

Study objectives
The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/03/2025, Wales Research Ethics Committee 1 Cardiff (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922940912; wales.rec1@wales.nhs.uk), ref: 25/WA/0026

Study design
Phase 1a/b Randomized double blinded placebo controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other, Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
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Interventions
The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Intervention Type
Drug

Pharmaceutical study type(s)
Biological/vaccine

Phase
Phase I

Drug/device/biological/vaccine name(s)
The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Primary outcome measure
The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Secondary outcome measures
The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Overall study start date
21/01/2025

Completion date
10/06/2026

Eligibility

Key inclusion criteria
The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
72

Key exclusion criteria
The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Date of first enrolment
27/03/2025

Date of final enrolment
11/06/2026

Locations

Countries of recruitment
United Kingdom

Study participating centre
MAC Clinical Research, Early Phase Unit
Neuroscience Centre of Excellence Citilabs1.0, Nelson Street
Manchester, Greater Manchester
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Study participating centre
MAC Clinical Research Centre
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Sponsor information

Organisation
Otsuka Pharmaceutical Development & Commercialization, Inc.

Sponsor details
2440 Research Boulevard
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Otsuka Pharmaceutical Development & Commercialization, Inc.

Results and Publications

Publication and dissemination plan
Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this Phase I study and the negligible benefit to the public of Phase I information. Results may be posted on or after the date of publication of full trial details.

Intention to publish date
14/01/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non-therapeutic clinical trials.

IPD sharing plan summary
Not expected to be made available