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

Type(s)
Principal investigator

Contact name
Dr Ashley Brooks

Contact details
MAC Clinical Research , Early Phase Suite Neuroscience Centre of Excellence Citilabs 1.0, Nelson Street
Manchester
United Kingdom
M13, 9NQ
+44 (0) 161 274 1603
ashleybrooks@macplc.com

Type(s)
Public, Scientific

Contact name
Dr Neel Bhatt

Contact details
MAC Clinical Research Centre 11 Tiger Court King's Drive King's Business Park Prescot Merseyside
United Kingdom

L34 1BH
+44 (0) 151 482 4700
neelbhatt@macplc.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1009721

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Other, Treatment

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

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(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.

Key secondary outcome(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.

Completion date
10/06/2026

Eligibility

Key inclusion criteria
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Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

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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
United Kingdom
M13 9NQ

Study participating centre
MAC Clinical Research Centre
11 Tiger Court, King's Drive King's Business Park
Prescot, Merseyside
United Kingdom
L34 1BH

Sponsor information

Organisation
Otsuka Pharmaceutical Development & Commercialization, Inc.

Funder(s)

Funder type
Industry

Funder Name
Otsuka Pharmaceutical Development & Commercialization, Inc.

Results and Publications

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