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

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

Submission date 28/03/2025	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol
Registration date 31/03/2025	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 04/06/2026	**Condition category** Other	[ ] Individual participant data [ ] 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

Integrated Research Application System (IRAS)
1009721

Sponsor code
X11-201-00001

Study information

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

Study objectives
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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

Primary study design
Interventional

Study design
Phase Ia/b randomised double-blind placebo-controlled study

Study type(s)
Treatment, Other

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)
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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
07/05/2026

Reason abandoned (if study stopped)
Otsuka has made a business decision to early terminate the trial. This decision is not based on safety reasons.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
42

Key exclusion criteria

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Date of first enrolment
31/03/2025

Date of final enrolment
06/05/2026

Locations

Countries of recruitment
United Kingdom

Study participating centre
MAC Clinical Research, Early Phase Unit
Neuroscience Centre of Excellence Citilabs1.0, Nelson Street
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Study participating centre
MAC Clinical Research Centre
11 Tiger Court, King's Drive King's Business Park
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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

IPD sharing plan summary
Not expected to be made available