

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

Submission date 28/03/2025	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/03/2025	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/05/2026	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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Type(s)

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Contact name

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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

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

Primary study design
Interventional

Study type(s)
Treatment, Other

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

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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)

Objectives no longer viable

Eligibility

Key inclusion criteria

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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

Manchester, Greater Manchester

England

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Study participating centre**MAC Clinical Research Centre**

11 Tiger Court, King's Drive King's Business Park

Prescot, Merseyside

England

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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