

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

|                                        |                                         |                                                                                                                         |
|----------------------------------------|-----------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>28/03/2025   | <b>Recruitment status</b><br>Recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                                  |
| <b>Registration date</b><br>31/03/2025 | <b>Overall study status</b><br>Deferred | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>31/03/2025       | <b>Condition category</b><br>Other      | <input type="checkbox"/> Individual participant data<br><input checked="" 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

Dr Ashley Brooks

### Contact details

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### Type(s)

Public, Scientific

### Contact name

Dr Neel Bhatt

### Contact details

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## 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

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### 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 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**

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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**

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

**Study outputs**

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |