

Phase I trial: BDD code: BDD23342

Submission date 05/02/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/02/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/02/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

The Health Research Authority (HRA) has approved 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)

Public, Scientific, Principal investigator

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT06728176

Integrated Research Application System (IRAS)

1009998

Protocol serial number

BDD23342/SCZ103

Study information

Scientific Title

Phase I trial: BDD code: BDD23342

Study objectives

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Ethics approval required

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Ethics approval(s)

approved 06/11/2024, London - Chelsea Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048181; chelsea.rec@hra.nhs.uk), ref: 24/LO/0703

Study design

Randomized double-blind placebo-controlled trial

Primary study design

Interventional

Study type(s)

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)

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Completion date

30/06/2025

Eligibility**Key inclusion criteria**

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

50 years

Sex

All

Key exclusion criteria

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Date of first enrolment

25/11/2024

Date of final enrolment

15/04/2025

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

BDD Pharma Ltd

Glasgow Royal Infirmary

84 Castle Street

Glasgow

United Kingdom

G4 0SF

Sponsor information

Organisation

Monument Therapeutics Ltd

Funder(s)

Funder type

Industry

Funder Name

Monument Therapeutics Ltd

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available because of the high commercial sensitivity of this phase I study and the negligible benefit to the public of phase I information.

IPD sharing plan summary

Not expected to be made available