ISRCTN52183349 https://doi.org/10.1186/ISRCTN52183349

Phase I trial: BDD code: BDD23342

Submission date 05/02/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 07/02/2025	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 19/02/2025	**Condition category** Other	[_] Individual participant data [X] 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

EudraCT/CTIS number
Nil known

IRAS number
1009998

ClinicalTrials.gov number
NCT06728176

Secondary identifying numbers
BDD23342/SCZ103

Study information

Scientific Title
Phase I trial: BDD code: BDD23342

Study objectives
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Ethics approval required
Ethics approval required

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

Secondary study design
Randomised controlled trial

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Dose response

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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Secondary outcome measures
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Overall study start date
06/11/2024

Completion date
30/06/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
up to 76

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
Scotland

United Kingdom

Study participating centre
BDD Pharma Ltd
Glasgow Royal Infirmary
84 Castle Street
Glasgow
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Sponsor information

Organisation
Monument Therapeutics Ltd

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Monument Therapeutics Ltd

Results and Publications

Publication and dissemination plan
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.

Intention to publish date
16/03/2026

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