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

Contact name
Dr Lyn Corry

ORCID ID
https://orcid.org/0009-0008-4224-4667

Contact details
BDD Pharma Ltd
Within Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom
G4 0SF
+44 141 552 8791
lyn.corry@bddpharma.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1009998

ClinicalTrials.gov (NCT)
NCT06728176

Protocol serial number
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

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)
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.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes