

Phase I trial, BDD code: BDD21288

Submission date 20/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/12/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/12/2023	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 12 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 (0)141 552 8791
lyn.corry@bddpharma.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1007309

Protocol serial number

IRAS 1007309

Study information

Scientific Title

Phase I trial, BDD code: BDD21288

Study objectives

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Ethics approval required

Ethics approval required

Ethics approval(s)

approved 27/09/2023, London - Westminster Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8066; westminster.rec@hra.nhs.uk), ref: 23/LO/0126

Study design

Pharmacoscintigraphic open-label crossover study

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)

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 12 months after the trial has ended.

Completion date

07/12/2023

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

60 years

Sex

Male

Total final enrolment

12

Key exclusion criteria

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Date of first enrolment

30/10/2023

Date of final enrolment

23/11/2023

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

BDD Pharma Ltd

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Cincinnati Children's Hospital Medical Center

Alternative Name(s)

Cincinnati Children's, Hospital Pediátrico y Centro Médico de Cincinnati, CCHMC

Funding Body Type

Government organisation

Funding Body Subtype

Other non-profit organizations

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date