ISRCTN98634795 https://doi.org/10.1186/ISRCTN98634795

Phase I trial, BDD code: BDD21288

Submission date 20/12/2023	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 21/12/2023	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 21/12/2023	**Condition category** Other	[ ] Individual participant data [ ] 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

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Additional identifiers

Integrated Research Application System (IRAS)
1007309

Study information

Scientific Title
Phase I trial, BDD code: BDD21288

Study objectives
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.

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

Primary study design
Interventional

Study design
Pharmacoscintigraphic open-label crossover study

Study type(s)
Other

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

Interventions
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.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(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.

Primary 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.

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
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.

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
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.

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