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

EudraCT/CTIS number
Nil known

IRAS number
1007309

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design
Pharmacoscintigraphic open-label crossover study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
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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

Pharmaceutical study type(s)
Pharmacokinetic, Scintigraphy

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/12/2022

Completion date
07/12/2023

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex

Male

Target number of participants
12

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
Scotland

United Kingdom

Study participating centre
BDD Pharma Ltd
Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Sponsor information

Organisation
BDD Pharma Ltd

Sponsor details
Bio-Imaging Centre
Basement Medical Block
Within Glasgow Royal Infirmary
84 Castle Street
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G4 0SF
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Sponsor type
Industry

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

Publication and dissemination plan
Full trial details will be published up to 12 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this phase I study and the negligible benefit to the public of Phase I information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date
07/12/2024

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