ISRCTN79577836 https://doi.org/10.1186/ISRCTN79577836

Phase I trial, BDD code: BDD22306

Submission date 10/10/2023	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 10/10/2023	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 10/10/2023	**Condition category** Not Specified	[ ] 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
1007120

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1007120

Study information

Scientific Title
Phase I trial, BDD code: BDD22306

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 22/08/2023, London Bridge Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048387; londonbridge.rec@hra.nhs.uk), ref: 23/LO/0037

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)
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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
08/01/2023

Completion date
22/12/2023

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
15

Key exclusion criteria
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Date of first enrolment
07/09/2023

Date of final enrolment
25/09/2023

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
Contera Pharma

Sponsor details
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Contera Pharma

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
24/10/2024

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