

Phase I trial, BDD code: BDD22306

Submission date 10/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/10/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/10/2023	Condition category Not Specified	<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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1007120

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 1007120

Study information

Scientific Title

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Study objectives

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Ethics approval required

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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

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)

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Completion date

22/12/2023

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

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

United Kingdom

Scotland

Study participating centre

BDD Pharma Ltd

Glasgow Royal Infirmary

84 Castle Street

Glasgow

United Kingdom

G4 0SF

Sponsor information

Organisation

Contera Pharma

Funder(s)

Funder type

Industry

Funder Name

Contera Pharma

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