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 15/05/2026	**Condition category** Not Specified	[_] Individual participant data [X] 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)
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

Primary study design
Interventional

Study design
Two-part exploratory single-centre crossover study in healthy volunteers

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
31/08/2026

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
All

Total final enrolment
43

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
07/09/2023

Date of final enrolment
21/05/2026

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre
BDD Pharma Ltd
Glasgow Royal Infirmary
84 Castle Street
Glasgow
Scotland
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

IPD sharing plan summary
Data sharing statement to be made available at a later date