ISRCTN93130126 https://doi.org/10.1186/ISRCTN93130126

Phase Ib Trial: 273391

Submission date 12/04/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/04/2024	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 30/10/2024	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

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Additional identifiers

EudraCT/CTIS number
2023-507340-36-00

IRAS number
1009618

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1009618

Study information

Scientific Title
Phase Ib Trial: 273391

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/04/2024, London - Riverside REC (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)2071048150; riverside.rec@hra.nhs.uk), ref: 24/LO/0180

Study design
Safety, tolerability, and pharmacokinetics study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Safety

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Tolerability, immunogenicity

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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Secondary outcome measures
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Overall study start date

03/04/2024

Completion date
10/02/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
55

Key exclusion criteria
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Date of first enrolment
03/04/2024

Date of final enrolment
03/06/2024

Locations

Countries of recruitment
Bulgaria

England

Georgia

Hungary

Moldova

Netherlands

Romania

United Kingdom

Study participating centre
Parexel Early Phase Clinical Unit (London)
Northwick Park Hospital
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Sponsor information

Organisation
Enthera S.r.l.

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Enthera S.r.l.

Results and Publications

Publication and dissemination plan

Full trial details will be published up to 30 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
10/08/2027

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non-therapeutic clinical trials

IPD sharing plan summary
Not expected to be made available