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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 [ ] 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.

Contact information

Type(s)
Principal investigator

Contact name
Dr David Steel

Contact details
Parexel Early Phase Clinical Unit - Northwick Park Hospital
Level 7 Watford Road
Harrow
London
United Kingdom
HA1 £UJ
+44 (0)1895614973
david.steel@parexel.com

Type(s)
Scientific

Contact name
Dr Filippo Canducci

Contact details
Via Visconti di Modrone Uberto 18
Milan
Italy
20122

+39 (0)3456306238
filippo.canducci@entherapharmaceuticals.com

Type(s)
Public

Contact name
Mrs Lisa maria Olson

Contact details
Via Visconti di Modrone Uberto 18
milan
Italy
20122
+39 (0)249533580
raffaella.maucci@entherapharmaceuticals.com

Additional identifiers

Clinical Trials Information System (CTIS)
2023-507340-36-00

Integrated Research Application System (IRAS)
1009618

Protocol serial number
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

Study type(s)
Safety

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)
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.

Key secondary outcome(s))
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Completion date
10/02/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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
United Kingdom

England

Bulgaria

Georgia

Hungary

Moldova

Netherlands

Romania

Study participating centre
Parexel Early Phase Clinical Unit (London)
Northwick Park Hospital
Level 7, Watford Road
Harrow
United Kingdom
HA1 3UJ

Sponsor information

Organisation
Enthera S.r.l.

Funder(s)

Funder type
Industry

Funder Name
Enthera S.r.l.

Results and Publications

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