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

# Phase Ib Trial: 273391

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| **Submission date**<br>12/04/2024 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol |
| **Registration date**<br>12/04/2024 | **Overall study status**<br>Deferred | [ ] Statistical analysis plan<br>[ ] Results |
| **Last Edited**<br>30/10/2024 | **Condition category**<br>Other | [ ] Individual participant data<br>[ ] 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

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## Additional identifiers

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

### Integrated Research Application System (IRAS)
1009618

### ClinicalTrials.gov (NCT)
Nil known

### 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))
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.

### 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
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United Kingdom
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# 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |