ISRCTN13906399 https://doi.org/10.1186/ISRCTN13906399

Phase 1 trial HMR code: 25-006

Submission date 25/09/2025	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 29/09/2025	**Overall study status** Deferred	
Last Edited 08/10/2025	**Condition category** Other	

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 30 months after the trial has ended.

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1012527

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HMR code: 25-006; sponsor code: MED-TSN-102

Study information

Scientific Title

Phase 1 trial HMR code: 25-006
The full scientific title will be published within 30 months after the end of the trial

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 30 months after the trial has ended.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/09/2025, London – Brent Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 20 7104 8128; brent.rec@hra.nhs.uk), ref: 25/LO/0462

Study design
Safety and pharmacokinetics trial in up to 36 healthy women

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Healthy volunteers

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 30 months after the trial has ended.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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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 30 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 30 months after the trial has ended.

Completion date
23/05/2026

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

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 30 months after the trial has ended.

Date of first enrolment
07/10/2025

Date of final enrolment
23/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Medicines Research (HMR)
Cumberland Avenue, Park Royal

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NW10 7EW

Sponsor information

Organisation
Medherant Limited

Funder(s)

Funder type
Industry

Funder Name
Medherant Limited

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