

Phase 1 trial HMR code: 25-006

Submission date 25/09/2025	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/09/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 30 months after the trial has ended.

Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1012527

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

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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

Secondary study design

Open label

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format.

Health condition(s) or problem(s) studied

Healthy volunteers

Interventions

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Intervention Type

Drug

Pharmaceutical study type(s)

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Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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Overall study start date

14/07/2025

Completion date

23/05/2026

Eligibility

Key inclusion criteria

Healthy human volunteer

Participant type(s)

Healthy volunteer

Age group

Mixed

Sex

Female

Target number of participants

Up to 36

Key exclusion criteria

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Date of first enrolment

07/10/2025

Date of final enrolment

23/02/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Hammersmith Medicines Research (HMR)
Cumberland Avenue, Park Royal
London
United Kingdom
NW10 7EW

Sponsor information

Organisation

Medherant Limited

Sponsor details

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Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Medherant Limited

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 1 study and the negligible benefit to the public of Phase I information. Results may be posted on or after the date of publication of full trial details.

Intention to publish date

23/11/2028

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