# Phase 1 trial HMR code: 25-006

Submission date 25/09/2025	<b>Recruitment status</b> Recruiting	[X] Prospectively registered  [ ] Protocol
Registration date	Overall study status	Statistical analysis plan
29/09/2025	Deferred	Results
Last Edited	Condition category	Individual participant data
08/10/2025	Other	[X] 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

## Type(s)

Principal investigator

#### Contact name

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### Type(s)

Scientific

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## Type(s)

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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**

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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

### Study type(s)

Other

## Health condition(s) or problem(s) studied

Healthy volunteers

#### **Interventions**

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## Intervention Type

Drug

#### Phase

Phase I

# Drug/device/biological/vaccine name(s)

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# Primary outcome(s)

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# 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

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#### 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

London United Kingdom 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 11/11/2025 No Yes