

Phase 1 trial HMR code: 23-001

Submission date 08/08/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/08/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/07/2025	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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1008009

Protocol serial number
IRAS 1008009; HMR code: 23-001; Sponsor code: MED-TSN-101

Study information

Scientific Title
Phase 1 trial HMR code: 23-001
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)
1. approved 24/09/2023, North East – York Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0) 207 104 8052; york.rec@hra.nhs.uk), ref: 23/NE/0096

2. approved 27/09/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 20 3080 6000; info@mhra.gov.uk), ref: CTA 52692/0001/001-0001

Study design

Safety and pharmacokinetics trial in up to 48 healthy women

Primary study design

Interventional

Study type(s)

Other, Safety

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

30/03/2026

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

40 years

Upper age limit

70 years

Sex

Female

Key exclusion criteria

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Date of first enrolment

25/09/2023

Date of final enrolment

19/09/2025

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Hammersmith Medicines Research Limited

Cumberland Avenue

London

United Kingdom

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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