

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 04/10/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English Summary

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
1008009

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 hypothesis
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)

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 24 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

Condition

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

23/06/2023

Overall study end date

04/03/2024

Eligibility

Participant inclusion criteria

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Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Female

Target number of participants

Up to 24

Participant exclusion criteria

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Recruitment start date

25/09/2023

Recruitment end date

04/12/2023

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Hammersmith Medicines Research Limited
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Sponsor information

Organisation
Medherant Limited

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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 1 information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date

04/09/2026

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