ISRCTN15245786 https://doi.org/10.1186/ISRCTN15245786

Phase 1 trial HMR code: 23-001

Submission date 08/08/2023	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol
Registration date 18/08/2023	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 17/07/2025	**Condition category** Other	[ ] Individual participant data [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.

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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 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)

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

Secondary study design
Open-label

Study setting(s)
Pharmaceutical testing facility, Other

Study type(s)
Other, Safety

Participant information sheet
Not available in web format

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

Pharmaceutical study type(s)
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Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure

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.

Secondary outcome measures
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.

Overall study start date
23/06/2023

Completion date
30/03/2026

Eligibility

Key inclusion 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.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
40 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
Minimum of 36 and up to 48 healthy post menopausal women

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
25/09/2023

Date of final enrolment

19/09/2025

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
04/12/2027

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