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

Phase 1 trial HMR code: 23-001

Submission date 08/08/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/08/2023	**Overall study status** Deferred	
Last Edited 17/07/2025	**Condition category** Other	

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
Dr Takahiro Yamamoto

Contact details
Hammersmith Medicines Research Limited
Cumberland Avenue
Park Royal
London
United Kingdom
NW10 7EW
+44 20 8961 4130
rec@hmrlondon.com

Type(s)
Scientific

Contact name
Mr John Burt

Contact details
Medherant Limited
The Venture Centre Sir William Lyons Road
University of Warwick Science Park
Coventry

United Kingdom
CV4 7EZ
+44 2476 323 060
j.burt@medherant.co.uk

Type(s)
Scientific

Contact name
Ms Gemma Clark

Contact details
Medherant Limited
The Venture Centre Sir William Lyons Road
University of Warwick Science Park
Coventry
United Kingdom
CV4 7EZ
+44 2476 323 060
g.clark@medherant.co.uk

Additional identifiers

Integrated Research Application System (IRAS)
1008009

Protocol serial number
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

Primary study design
Interventional

Study design
Safety and pharmacokinetics trial in up to 48 healthy women

Study type(s)
Other, Safety

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

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary 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.

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
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