ISRCTN16253842 https://doi.org/10.1186/ISRCTN16253842

Phase 1 trial: MAC Clinical Research: MAC180

Submission date
22/02/2024

Recruitment status
No longer recruiting

Registration date
23/02/2024

Overall study status
Deferred

Last Edited
23/02/2024

Condition category
Not Specified

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
The Health Research Authority (HRA) has approved 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)
Public, Scientific

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Type(s)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1008854

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1008854; OMS906-NHV-004

Study information

Scientific Title
Phase 1 trial: MAC Clinical Research: MAC180
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 11/01/2024, Wales Research Ethics Committee 1 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2920 785738; Wales.REC1@wales.nhs.uk), ref: 23/WA/0330

2. Approved 12/01/2024, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0) 20 3080 6000;; info@mhra.gov.uk), ref: 49709/0006/001-0001

Study design
Phase 1 single dose study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied
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Interventions
The Health Research Authority (HRA) has approved 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
Not Specified

Primary outcome measure
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Secondary outcome measures
The Health Research Authority (HRA) has approved 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
29/11/2023

Completion date
30/10/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Not Specified

Sex
Both

Target number of participants

Key exclusion criteria
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Date of first enrolment
29/02/2024

Date of final enrolment
30/10/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MAC Clinical Research Blackpool
Clinical Research Centre
Kaman Court
1 Faraday Way
Blackpool
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Sponsor information

Organisation
Omeros Corporation (United States)

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Sponsor type
Industry

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ROR
https://ror.org/01r5k6556

Funder(s)

Funder type
Industry

Funder Name
Omeros Corporation

Alternative Name(s)
Omeros, Omeros Corp, OMS

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/04/2027

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 nontherapeutic clinical trials.

IPD sharing plan summary
Not expected to be made available