ISRCTN15751828 https://doi.org/10.1186/ISRCTN15751828

Phase I trial - 2021-006930-37

Submission date 15/07/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 15/07/2022	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 03/10/2025	**Condition category** Other	[_] Individual participant data [X] 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

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2021-006930-37

Integrated Research Application System (IRAS)
1004695

Central Portfolio Management System (CPMS)
52873

Study information

Scientific Title
Phase I trial - 2021-006930-37
[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
Old ethics approval format

Ethics approval(s)
1. Approved 16/06/2022, London -Chelsea Research Ethics Committee (2 Redman Place, Stratford, London E20 1JQ, UK: +44(0)207 1048064; chelsea.rec@hra.nhs.uk), ref: 22/LO/0352
2. Approved 17/06/2022, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; (+44 (0)20 3080 6000; info@mhra.gov.uk); ref: CTA 49709/0003/001-0001

The HRA has approved deferral of publication of trial details.

Study design
Interventional open-label phase I study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Drug

Phase
Phase I

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

Key secondary outcome(s))
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

Completion date
12/04/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

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Date of first enrolment
30/08/2022

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St. James' University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7T

Sponsor information

Organisation
Omeros Corporation (United States)

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No