

Phase I trial - 2021-006930-37

Submission date 15/07/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/07/2022	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/10/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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)

Scientific

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Type(s)

Principal investigator

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Additional identifiers

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

Integrated Research Application System (IRAS)
1004695

Protocol serial number
IRAS 1004695, 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)

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Key secondary outcome(s)

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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