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 01/11/2022	**Condition category** Other	[_] 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

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Scientific

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Additional identifiers

EudraCT/CTIS number
2021-006930-37

IRAS number
1004695

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)

Hospital

Study type(s)
Other

Participant information sheet
Not available in web format

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 measure
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

Secondary outcome measures
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Overall study start date
19/04/2022

Completion date
12/04/2025

Eligibility

Key inclusion criteria

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Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
12

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
England

United Kingdom

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

Sponsor information

Organisation

Omeros Corporation (United States)

Sponsor details
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Sponsor type
Industry

Website
http://www.omeros.com/

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
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 I study and the

negligible benefit to the public of phase I information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date
01/10/2027

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

Study outputs

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