# Phase I trial - 2021-006930-37

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

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Samantha Magazu

#### Contact details

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# Type(s)

Principal investigator

#### Contact name

Dr Morag Griffin

#### Contact details

St James University Hospital Leeds United Kingdom LS9 7TF

# Additional identifiers

#### Clinical Trials Information System (CTIS)

2021-006930-37

#### Integrated Research Application System (IRAS)

1004695

### ClinicalTrials.gov (NCT)

Nil known

#### 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes