# Phase 1 trial: MAC Clinical Research: MAC180

Submission date	Recruitment status	[X] Prospectively registered
22/02/2024	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
23/02/2024	Deferred	Results
Last Edited	Condition category	Individual participant data
23/02/2024	Not Specified	[] 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

#### Contact name

Dr Omeros Clinical Trial Information

#### Contact details

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### Type(s)

Principal investigator

#### Contact name

Dr Hamzah Malik

### Contact details

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# Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

1008854

## ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## Study type(s)

Other

# 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(s)

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## 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

30/10/2024

# **Eligibility**

### Key inclusion criteria

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### Participant type(s)

Healthy volunteer

### Healthy volunteers allowed

No

### Age group

**Not Specified** 

#### Sex

All

### 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

United Kingdom

England

Study participating centre MAC Clinical Research Blackpool

Clinical Research Centre Kaman Court 1 Faraday Way Blackpool United Kingdom FY2 0JH

# 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