# Phase I trial: MM-120-101

Submission date	Recruitment status	Prospectively registered
14/05/2024	No longer recruiting	<pre>Protocol</pre>
Registration date	Overall study status	Statistical analysis plan
21/05/2024	Deferred	Results
Last Edited	Condition category	Individual participant data
20/05/2024	Other	<ul><li>Record updated in last year</li></ul>

#### 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, Principal Investigator

#### Contact name

Dr David Gregory

#### Contact details

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# Additional identifiers

## **EudraCT/CTIS** number

Nil known

#### IRAS number

1007602

#### ClinicalTrials.gov number

Nil known

#### Secondary identifying numbers

IRAS 1007602

# Study information

#### Scientific Title

Phase I trial: MM-120-101

#### **Study objectives**

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#### Ethics approval required

Ethics approval required

#### Ethics approval(s)

Approved 18/09/2023, Wales Research Ethics Committee 1 Cardiff (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road, East Cardiff, CF11 9AB, United Kingdom; 02922940912; wales.rec1@wales.nhs.uk), ref: 23/WA/0112

#### Study design

Phase 1 study in 30 healthy volunteers

#### Primary study design

**Not Specified** 

#### Secondary study design

#### Study setting(s)

Pharmaceutical testing facility

#### Study type(s)

Other, Safety

#### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

#### Health condition(s) or problem(s) studied

Healthy volunteers

#### **Interventions**

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#### Intervention Type

Drug

#### Pharmaceutical study type(s)

Pharmacokinetic

#### 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

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.

#### Overall study start date

18/04/2023

#### Completion date

19/12/2023

# **Eligibility**

#### Key inclusion criteria

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### Participant type(s)

Healthy volunteer

#### Age group

Adult

#### Sex

Both

#### Target number of participants

30

#### Key exclusion criteria

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#### Date of first enrolment

13/10/2023

#### Date of final enrolment

04/12/2023

## Locations

### Countries of recruitment

England

**United Kingdom** 

# Study participating centre MAC Clinical Research Liverpool

11 Tiger Court King's Business Park Liverpool United Kingdom L34 1BH

# Study participating centre MAC Clinical Research Manchester

Citylabs 1.0 Nelson St Manchester United Kingdom M13 9NQ

# Sponsor information

### Organisation

Mind Medicine Inc

#### Sponsor details

One World Trade Centre, Suite 8500 New York United States of America NY 10007 +1 513 476 9666 aengel@mindmed.co

#### Sponsor type

Research organisation

#### Website

# Funder(s)

#### Funder type

Research organisation

#### Funder Name

Mind Medicine Inc

# **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. Results will be posted on or after the date of publication of full trial details.

#### Intention to publish date

19/06/2026

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to commercial sensitivity of the data

## IPD sharing plan summary

Not expected to be made available