

# Phase I trial MM-402-101

<b>Submission date</b> 14/05/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/05/2024	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/05/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input 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)

Public, Scientific, Principal investigator

### Contact name

Dr David Gregory

### Contact details

11 Tiger Court  
Kings Drive Prescott  
Liverpool  
United Kingdom  
L34 1BH  
+44 (0)1514824700  
davidgregory@macplc.com

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

1007767

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

## Study information

### Scientific Title

Phase I trial MM-402-101 [The full scientific title will be published within 30 months after the end of the trial]

### Study objectives

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.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 24/10/2023, Wales Research Ethics Committee 1 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road, Cardiff, CF11 9AB, United Kingdom; +44 (0)2922940912; wales.rec1@wales.nhs.uk), ref: 23/WA/0135 and CTA 57953/0002/001-0001

### Study design

Phase I study in 40 healthy volunteers

### Primary study design

Interventional

### Study type(s)

Other, Safety

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

Healthy volunteers

### 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

Drug

### Phase

Phase I

### Drug/device/biological/vaccine name(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.

### Primary 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.

### **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**

14/10/2024

## **Eligibility**

### **Key inclusion criteria**

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.

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

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.

### **Date of first enrolment**

10/05/2024

### **Date of final enrolment**

30/09/2024

## **Locations**

### **Countries of recruitment**

United Kingdom

England

**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.

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Mind Medicine Inc.

## Results and Publications

### 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 the commercial sensitivity of the data

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
-------------	---------	--------------	------------	----------------	-----------------

