

Phase I trial MM-402-101

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

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1007767

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

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Ethics approval required

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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

Secondary study design

Non randomised study

Study setting(s)

Other

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)

Not Applicable

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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Overall study start date

18/07/2023

Completion date

14/10/2024

Eligibility**Key inclusion criteria**

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Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

40

Key exclusion criteria

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Date of first enrolment

10/05/2024

Date of final enrolment

30/09/2024

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 Center, Suite 8500
New York
United States of America
NY 10007
+1 (0)513 476 9666
aengel@mindmed.co

Sponsor type

Industry

Funder(s)

Funder type

Industry

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

14/04/2027

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