ISRCTN15997848 https://doi.org/10.1186/ISRCTN15997848

Phase I trial MM-120-102

Submission date 17/05/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 21/05/2024	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 21/05/2024	**Condition category** Other	[ ] Individual participant data [ ] 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 Prescot
Liverpool
United Kingdom
L34 1BH
+44 (0)1514824700
davidgregory@macplc.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1009246

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1009246

Study information

Scientific Title
Phase I trial MM-120-102 [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 22/03/2024, 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: 24/WA/0003 and CTA 57953/0003/001-0001

Study design
Phase I study in 32 healthy volunteers

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

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
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

Pharmaceutical study type(s)
Pharmacokinetic

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 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
26/01/2024

Completion date
29/08/2024

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

Age group
Adult

Sex
Both

Target number of participants
32

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
08/05/2024

Date of final enrolment
17/06/2024

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

Website
https://mindmed.co/

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
28/02/2027

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 commercial sensitivity of the data

IPD sharing plan summary
Not expected to be made available