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Safety, tolerability, pharmacokinetics, pharmacodynamics and exploratory efficacy of intravenous dosing of SPL026 drug product (N, N-dimethyltryptamine fumarate; DMT Fumarate [A Serotonergic Psychedelic]) alone or in combination with selective serotonin reuptake inhibitors in patients with major depressive disorder

Submission date
03/04/2024

Recruitment status
No longer recruiting

Registration date
30/04/2024

Overall study status
Completed

Last Edited
10/06/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The purpose of this study is to test a drug called SPL026 (the 'study drug') that is being developed for the treatment of MDD.
Major depressive disorder, known as 'depression', is a common mental illness affecting about 280 million people worldwide. Depression affects people in different ways and causes a wide range of symptoms, such as feelings of unhappiness and hopelessness, losing interest in things they used to enjoy, and anxiety. The symptoms can also be physical, including feeling constantly tired, problems with sleep, and aches and pains. There are existing treatments for depression, but they don't work well in some patients and more treatment options are needed. DMT (the study medicine, also known as SPL026) is being developed as an experimental new treatment for depression in combination with therapy sessions. It acts at sites in the brain (called serotonin receptors) that are associated with mood and mental health. Previous research on a similar psychedelic medicine (psilocybin), which works on the same sites in the brain as DMT, suggests that psilocybin may be an effective treatment for depression, when used alongside talking therapy. So, psychedelic medicines like psilocybin and DMT offer a different treatment method to traditional medicines. We hope DMT, when given alongside therapy sessions, will be an effective treatment for depression, and will therefore give patients with depression more treatment options.

It is important for you to know that when you receive DMT, you'll likely have a psychedelic experience or 'trip'. During your Screening visit and before you're dosed, we'll explain what to expect from a psychedelic experience and how to respond to it. We'll also show you where you'll stay on the ward and receive your dose, and you'll meet the staff who'll look after you during the study.
The study drug is 'investigational', which means that it has not yet been approved for marketing by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK, or the Food and Drug Administration (FDA) in the USA.
The main aims and questions of this study are:
• To assess the safety and tolerability of the study drug, given as a slow injection into a vein in the arm, to patients already taking a single SSRI antidepressant, compared to patients not taking an SSRI antidepressant.
• To see how the body absorbs and removes the study drug when taken alone and in combination with a single SSRI antidepressant.
• To assess the effect of the study drug on the body, mood, feelings, thoughts and beliefs when taken alone and in combination with a single SSRI antidepressant.

Who can participate?
We plan to enrol up to 24 patients with mild to severe MDD, who will be divided into the two following groups:
1. Patients with mild to severe MDD who are currently taking an SSRI antidepressant that is ineffective in fully relieving depression. Patients in this cohort must be on a stable dose, with no intention of making any changes, for at least 6 weeks before Screening. This group of patients will be known as the 'Test Cohort'. This cohort will comprise of up to 18 patients.
2. Patients with mild to severe MDD who have not received any medication for their depression for at least 6 months before dosing, with the exception of monoamine oxidase inhibitor class antidepressants, which can have been taken up to 3 months before Screening. This group of patients will be known as the 'Control Cohort'. This cohort will comprise of up to 6 patients. In the Test Cohort, 2 patients will be dosed first; the rest of the group will then be dosed at least 48 hours later if thought safe to do so by the research team after checking how the first 2 patients responded to the medication.

What does the study involve?
During this study, you will be given a single dose of DMT (27.5 mg). The study medication will be administered by intravenous (IV) infusion, allowing the controlled administration of the study medication directly into your bloodstream using a plastic cannula that will be fitted in a vein in your arm. In this study, DMT will be administered during a 10-minute IV infusion. If required, the infusion can be stopped at any time for safety reasons. In order to ensure your safety, the study medication will be administered alongside psychological support from a therapist team (which will include a psychiatrist and/or up to 2 therapists). The research team and your therapist team will be specially trained to prepare and support you through this experience. Therapists will be professionally qualified and work to an ethical guideline, against which they will be monitored throughout the trial. Your therapist team will be with you at all times and will be able to help you if you get anxious or distressed during the psychedelic experience. You will be given the study drug in a calm private room. A bespoke soundtrack will be played in the room, and you will be encouraged to wear eyeshades and headphones. The psychedelic effects are only temporary (typically lasting for 20 minutes) and you will be assessed for safety before being discharged from the research unit on Day 2.

What are the possible risks and benefits of participating?
In this study, we plan to test a single dose of 27.5 mg DMT, given by slow injection into a vein in the arm over 10 minutes, alone or in combination with a single SSRI antidepressant. This dose

level has been based on results from a previous study investigating a single dose of DMT in 32 healthy volunteers. In that study, 24 healthy volunteers (who've never taken a psychedelic substance before) received up to 21.5 mg DMT given by a slow, 2-part injection into a vein over 10 minutes. There were no important side effects, but some people had headaches, or a mild, short-lived burning sensation at the site on their arm where they received their injection (the sensation lasted about 10 minutes – the duration of the injection). At least 100 volunteers in other studies have received doses of up to 0.25 mg/kg DMT (17 mg DMT for a 70 kg person), by injection into a vein over a few seconds. Those studies were in people who'd previously taken psychedelic substances. The doses of DMT tested were considered safe. DMT has been taken by people for centuries either by smoking or inhaling it, or as a hallucinogenic brew (ayahuasca), which is used in spiritual ceremonies in some South American countries.

The dose of DMT we will test in this study (27.5 mg) is higher than that tested in previous studies (21.5 mg), but we don't expect it to give higher blood levels than those in previous studies, because we'll give your dose by a single, continuous slow injection over 10 minutes. The dose of DMT you'll receive is likely to cause a psychedelic experience or 'trip', which is expected to last about 20 minutes. You may experience: visual imagery or hallucinations (seeing colourful patterns, or seeing or hearing things that aren't real), a sense of being detached from your thoughts or feelings, changes in your sense of time and space, out-of-body experiences, disorientation or confusion, anxiety, intense emotions such as happiness or grief. Sometimes people experience unpleasant images and sounds and may also 'relive' painful memories or traumas. In published research into psychedelic treatments for depression, difficult emotions and upsetting content experienced during the 'trip' are considered therapeutically beneficial, as they can lead to important insights. You'll have the support and guidance of expert therapists to help you interpret and deal with any experiences you may have during your trip. If you become very upset or agitated after your dose, the study doctor may give you a licensed medicine to help you relax. Before you take part in the study, we'll explain what you should expect from a psychedelic trip and how to respond to it (while on the ward and once you've gone home), and you'll have an interview with a psychiatrist to make sure you're suitable to take part. We'll monitor you closely during and after your dose – the therapist team and a nurse will be with you, and a psychiatrist will be available if needed. We'll stop the injection of study medicine if you ask us to, or if we think it's necessary. Before and after your dose, the study therapist team will talk to you about your experience. If you were to have a challenging experience or negative reaction to DMT during or after the session, our research team will be able to help you. Challenging experiences can be triggered by psychedelic drugs, such as DMT, and are usually temporary and resolve with reassurance and support. The chances are that we won't need to use any medication at all, and any psychedelic effects will be short-lived and resolve of their own accord. Your experience with DMT might make you feel differently about yourself and your life, so we'll advise you not to make any life changing decisions for 6 weeks following the session. As with any new medicine, we don't yet know all its side effects. In any clinical trial, there is a risk of an unexpected, serious reaction to the study medicine, which could be potentially life-threatening. In clinical studies of DMT, some people had physical effects, such as increased blood pressure and heart rate, feeling sick, and headaches. We'll monitor your heart rate and blood pressure during the study. In the unlikely event that your heart rate or rhythm or your blood pressure changes significantly, the study doctor will take the appropriate steps to reverse this side effect. If deemed necessary, you may be referred to the hospital emergency department and/or a cardiologist for further investigations and/or treatments. You will be closely monitored throughout the study, and questions about suicidal thoughts and feelings will be frequently asked throughout the study using a rating scale. If your mental health were to deteriorate significantly during any point of the study and we had serious concerns about your safety, then we would be obliged to involve local mental health services to determine how best to manage your condition. The study drug's effect on the body may change when the drug is taken in

combination with another drug, which can result in either a decrease or increase in the effects of either, or both, drugs. This could have potential side effects. The study team will carefully evaluate any prescription or non-prescription medications that you are taking at your Screening visit.
So-called 'flashbacks', or a sense of re-experiencing psychedelic drug effects when no drug has been taken has been described in scientific literature with recreational use of drugs such as DMT. If this occurs it is usually not a problem but please do let the research team know, who can support or guide you. A very rarely reported side effect of taking psychedelics as recreational drugs is something called hallucinogen-induced persistent perceptual disorder (HPPD). People who report symptoms of HPPD may see haloes around objects, light trails and alterations in the colour and shape of objects. This effect is seen very rarely following recreational use of psychedelic drugs and has not been reported when psychedelic drugs have been taken in scientific and clinical studies.

As with any new medicine, the study medicine might affect an unborn child. You must not take part in the study if you are pregnant or want to become pregnant at the time of the study. Pleasetell us straight away if you think you or your partner might be pregnant. We would want to keep in touch with you until the end of the pregnancy, to find out if the study medicine had affected your unborn child – we'd ask your permission to do that. The study medicine may affect your concentration or judgement, so you shouldn't drive or operate machinery for 24 hours after your dose (if you leave MAC for any reason, before the scheduled time). You will be carefully monitored during your time on the study, although this does not mean these side effects could not occur. It is important that you report to your study doctor all symptoms and side effects that you may experience, as soon as they appear, whether or not you think they are related to the study medication. You will always be closely looked after throughout the study. Although all possible precautions are taken to prevent serious side effects, if such a side effect occurs, you may need to be admitted into hospital. Depending on the type of side effect, a medical specialist may be asked to take over your care. If you're ill while you're on the ward, we'll give you any immediate treatment you need. If you're ill after leaving the ward, call usas soon as you can. We might need to see you again, but if you weren't well enough to travel, you'd need help from a local doctor or hospital. One of our doctors is always available on the telephone to discuss medical problems with you or with other doctors. We'll give you a medical alert card with some information about the study and contact numbers of MAC doctors. When you've left the ward, carry the card with you at all times until your End-of-Study video call. If you visit other healthcare professionals (such as a doctor, nurse or dentist), show them the card. Bring your medical alert card with you whenever you visit the ward. We will also provide you with an out of hours emergency contact number for a member of staff.

We don't know if you'll get any long-lasting medical benefit from taking DMT in this trial. It's important for you to know that you can't carry on taking DMT after the study, even if you do get some benefit from it. You may benefit from regular conversations with the study psychiatrist and therapist team. Our screening tests might be of benefit if we find an important medical problem, but they could reveal something you'd prefer not to know about. If you take part, you'll be helping medical research.
DMT is a Class A illegal drug – we have a special licence to be able to give it to volunteers in this study.

The Sponsor, and/or others working with the Sponsor, will own the results of this study. The results might have commercial or intellectual property value and might be used to apply for patents. You won't receive any financial benefit that might come from the study.

Where is the study run from?
Cybin UK Ltd.

When is the study starting and how long is it expected to run for?
April 2022 to August 2023

Who is funding the study?
Cybin IRL Ltd., based in Ireland.

Who is the main contact?
Ellen James, ellen@cybin.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
2022-001767-27

IRAS number
1005892

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CT026_004, IRAS 1005892

Study information

Scientific Title
An open-label study investigating the safety, tolerability, pharmacokinetics, pharmacodynamics and exploratory efficacy of intravenous dosing of SPL026 drug product (N, N-

dimethyltryptamine fumarate; DMT Fumarate [A Serotonergic Psychedelic]) alone or in combination with selective serotonin reuptake inhibitors in patients with major depressive disorder

Study objectives
SPL026 with support therapy is as safe and well tolerated following intravenous (IV) administration in major depressive disorder (MDD) patients currently taking a selective serotonin reuptake inhibitor (SSRI) that is ineffective in fully relieving their depression (Test Cohort), compared to a single IV administration of SPL026 DP with therapy in MDD patients who are not currently taking any pharmacological treatment for their depression (Control Cohort).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/08/2022, London – Brent Research Ethics Committee (80 London Road, Skipton House, London, SE1 6LH, United Kingdom; +44 20 7104 8229; Brent.rec@hra.nhs.uk), ref: 22/LO/0431

Study design
Phase Ib open-label study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Safety, Efficacy

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
Major Depressive Disorder (MDD)

Interventions
This is a Phase Ib, open-label study to determine the safety, tolerability, PK profile, PD and exploratory efficacy of a single IV dose of SPL026 DP in MDD patients currently taking an SSRI that is ineffective in fully relieving their depression (Test Cohort), compared to a single IV dose of SPL026 DP with therapy in MDD patients who are not currently taking any pharmacological treatment for their depression (Control Cohort).
It is planned to enrol up to 24 MDD patients, who will be included in either:
a) The Control Cohort (consisting of up to 6 MDD patients who are not currently receiving any

pharmacological treatment for their depression), or
b) The Test Cohort (consisting of up to 18 MDD patients currently taking an SSRI that is ineffective in fully relieving their depression)

This study will evaluate a single dose of SPL026 DP (27.5 mg) administered as a continuous 10-minute IV infusion via a cannula. Two patients in the Test Cohort will be dosed initially; the remaining patients in the Test Cohort will commence treatment after a satisfactory review of the safety data up to a minimum of 48 hours postdose from the first 2 patients, if deemed safe to do so by the Investigator.

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacodynamic

Phase
Phase I

Drug/device/biological/vaccine name(s)
SPL026 (N, N-dimethyltryptamine fumarate; DMT)

Primary outcome measure
1. Safety will be evaluated by the monitoring of adverse events (AEs), vital signs (blood pressure, heart rate and temperature), 12-lead electrocardiogram (ECG) evaluations, clinical laboratory assessments (haematology, clinical chemistry, coagulation and urinalysis), cannulation site reactions and physical examination findings. To Day 29.
2. Suicidal ideation and behaviour will be evaluated using the Columbia Suicide Severity Rating Scale (C-SSRS). To Day 29.
3. Tolerability will be evaluated by reviewing the therapists' notes that document the subjective psychedelic effects and a tolerability assessment. To Day 2.

Secondary outcome measures
1. PK - IV using frequent blood sampling from 4 hours pre-dose to 4 hours post-dose.
2. PD – Presence and intensity of dysfunctional attitudes measured using Dysfunctional Attitude Scale (DAS) on Day -1, 8, 15 and 29.
3. PD – One's responses to depressed mood measured using Ruminative Responses Scale (RRS) on Day -1 and 29.
4. PD – the degree to which someone feels connected to others in their social environment measured using Social Connectedness Scale-Revised (SCS-R) on Day -1, 15 and 29.
5. PD – Wellbeing using The Warwick-Edinburgh Mental Well-being Scale (WEMWBS) on Day -1, 15 and 29.
6. PD – Individual's level of psychological insight following a psychedelic experience and accompanied behavioural changes measured using Psychological Insight Scale (PIS) on Day -1, 15 and 29.
7. PD – The extent of any emotional, psychological or physical changes the patient has experienced in the time since being dosed measured using Post-treatment Changes Scale (PTCS) on Day 15 and 29.
8. PD – preparedness for the psychedelic experience measured with the Psychedelic Predictor Scale on Day 1 (predose).
9. PD – Subjective experience using Mystical Experience Questionnaire (MEQ), The Ego

Dissolution Inventory (EDI), Emotional Breakthrough Inventory (EBI), Challenging Experience Questionnaire (CEQ) and Visual Analogue Scale (VAS) at Day 1 post-dose (before the post-dose integration session) and using Intensity Rating Visual Analogue Scale (IRVAS) at Day 1 post-dose (after the post-dose integration session).

Overall study start date
28/04/2022

Completion date
03/08/2023

Eligibility

Key inclusion criteria
1. Patients with MDD, as defined in the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) of a mild to severe degree (scoring ≥14 on the 17-item HAM-D).
2. Patient is aged ≥18 years.
3. Patient has a body mass index (BMI) of 18 to 33.9 kg/m2, inclusive.
4. Test Cohort Only: Patient is currently on a stable dose of an unspecified single SSRI alone and not in combination with any other psychiatric medications, for at least 6 weeks prior to Screening with no intention of making any changes.
5. Patient has tried at least one approved method of treatment for their depression.
6. Patient has not been administered any Monoamine Oxidase-Inhibitor (MAO-inhibitor) class antidepressants for at least 3 months prior to Screening.
7. No psychedelic drug use 6 months prior to dosing (excluding the study drug) until the end of the study.
8. Registered with a General Practitioner (GP) in the UK.
9. Under the care of a healthcare professional who can confirm the diagnosis and previous treatment received by the patient.
10. Sufficient intelligence to understand the nature of the trial and any hazards of participation in it. Ability to communicate satisfactorily with the Investigator and therapist team to participate in, and comply with the requirements of, the entire trial.
11. Healthy as determined by a responsible physician, based on no clinically significant findings from medical evaluation including medical history, a physical examination, concomitant medication, vital signs, 12-lead Electrocardiogram (ECG) and clinical laboratory evaluations (including haematology, coagulation, biochemistry and urinalysis) at the Screening visit and admission.
12. Agree to follow the contraception requirements of the trial.
13. Willing to be contacted by email and telephone and video call.
14. Proficient in reading and writing English sufficient to complete questionnaires.
15. Willing to give written consent to have data entered into The Over-volunteering Prevention System.
16. Provision of giving written informed consent, which includes compliance with the requirements and restrictions listed in the consent form, and after the having the opportunity to discuss the trial with the Investigator or their delegate.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
24

Total final enrolment
18

Key exclusion criteria
1. Patient meets the DSM-5 criteria for substance abuse disorder, as assessed the Mini International Neuropsychiatric Interview (MINI) Version 7.0.2 at Screening, or a positive urine drugs of abuse result at Screening or Day -1 (excluding cannabis which is permitted to be taken up to 24 hours before each trial visit, but which may be detected in urine). Repeat tests may be considered by the Investigator with justification.
2. Current or clinically relevant history of a psychotic disorder, including schizophrenia, psychosis, bipolar disorder, delusional disorder, paranoid personality disorder, schizoaffective disorder, borderline personality disorder, emotionally unstable personality disorder or panic disorder, as assessed by a structured clinical interview (MINI, Version 7.0.2) at Screening. 3. In first-degree relatives, a clinically relevant history of a psychotic disorder, including schizophrenia, psychosis, bipolar disorder, delusional disorder, paranoid personality disorder or schizoaffective disorder.
4. Significant history of mania (as determined by the Investigator and medical records, in agreement with the Sponsor's Medical Monitor).
5. Psychiatric condition judged to be incompatible with establishment of rapport with the therapy team and/or safe exposure to DMT, based on the Investigator's clinical evaluation (e.g., borderline personality disorder).
6. Significant suicide risk, as defined by: · Suicidal ideation as endorsed on items 4 or 5 on the C-SSRS within 1 year prior to Screening or on Day -1, or Suicidal behaviours within 1 year prior to Screening, or History of serious suicide attempts in lifetime (i.e., those that require hospitalisation), or Clinical assessment of significant suicide risk during Patient interview.

General Medical Exclusion Criteria
Patients with any of the following will be excluded from study participation:
1. Control Cohort Only: Patient has received any pharmacological treatment for MDD within 6 months of dosing, with the exception of MAO-inhibitors which they cannot have received within 3 months of Screening.
2. Test Cohort Only: Ongoing use of antidepressant augmentation or combination therapies, other than a single SSRI.
3. Clinically relevant history of abnormal physical or mental health interfering with the study as determined by medical history and physical examinations obtained during Screening, as judged by the Investigator (including [but not limited to]: neurological, psychiatric, endocrine, thyroid, cardiovascular, respiratory, GI, hepatic, haematological, musculoskeletal, immunological, renal, connective tissue diseases or disorders or any other medically relevant condition as judged by

the Investigator).
4. Clinically relevant abnormal laboratory results (including hepatic and renal panels, complete blood count, chemistry panel and urinalysis), 12-lead ECG and vital signs, or physical findings at Screening and/or Day -1 as judged by the Investigator, that in the Investigator's opinion may constitute a risk for an individual who is exposed to DMT. In case of uncertain or questionable results, tests performed during Screening may be repeated to confirm eligibility or judged to be clinically irrelevant for otherwise healthy MDD patients.
5. Any other acute condition or infection, or history of chronic illness or condition, that could interfere with, or for which the treatment might interfere with, the conduct of the study as outlined in this Protocol, or that would, in the opinion of the Investigator, pose an unacceptable risk to the patient in this study.
6. Current or previous medical history of any significant cardiovascular conditions, such as: coronary heart disease, arrhythmia, clinically significant ECG abnormality, artificial heart valve or current hypertension. In addition, any family history of long QT syndrome or sudden death (due to a cardiac event).
7. AST, ALT, gamma-glutamyl transferase (GGT) or total bilirubin levels ≥1.5 × ULN at Screening or Day -1. Isolated raised bilirubin for patients suspected or confirmed to have Gilbert's syndrome can be permitted at the Investigator's discretion. These laboratory evaluations may be repeated once at the discretion of the Investigator. If the repeat test is within the reference range of 1.5 × ULN, the patient may be included only if the Investigator considers that the previous finding will not introduce additional risk factors and will not interfere with interpretation of safety data.
8. Psychological or neurological (e.g., medical conditions associated with seizures or convulsions) chronic illness or condition, as deemed relevant by the Investigator, in agreement with the Sponsor's Medical Monitor.
9. Blood pressure and HR in the supine and standing position outside of the following ranges at Screening:
a. Systolic BP: 90 to 140 mmHg.
b. Diastolic BP: 40 to 90 mmHg.
c. Heart rate: 40 to 100 bpm.
Borderline values (i.e., values that are within 5 mmHg of the range for BP, or 5 bpm of the range for HR) will be repeated. Patients can be included if the repeat value is within the specified range or still borderline but deemed not clinically significant by the Investigator.
10. QT interval corrected for HR using Fridericia's formula (QTcF) values ≥450 msec (males) or ≥470 msec (females) (physician to determine which limit value to use on a per patient basis) at Screening or predose on Day 1. Triplicate measurements will be made; mean QTcF values ≥450 msec (males) or ≥470 msec (females) (physician to determine which limit value to use on a per patient basis) will lead to exclusion. A repeat (in triplicate) is permitted on one occasion for determination of eligibility at the discretion of the Investigator. If the repeat test is within the reference range, the patient may be included only if the Investigator considers that the previous finding will not introduce additional risk factors and will not interfere with interpretation of safety data.
11. Presence of clinically significant ECG abnormalities at the Screening visit, as defined by medical judgement.
12. Positive test for hepatitis B surface antigen (HBsAg), anti-hepatitis C antibody (anti-HCV) or human immunodeficiency virus I and II (anti-HIV I/II) at Screening. 13. Use of any serotonergic psychedelics (mescaline, LSD, psilocybin and DMT) within 6 months prior to dosing.
14. Intake of >21 units of alcohol weekly, and the inability to refrain from alcohol use from 24 hours prior to each visit during the study. One unit is equivalent to a 285 mL glass of full-strength beer or 1 (30 mL) measure of spirits or 1 glass (100 mL) of wine.
15. Unable to refrain from smoking cigarettes and e-cigarettes from 4 hours prior to dosing until at least 4 hours after dosing, and while in the CRU. Patients will be allowed to use a low dose

nicotine patch (≤20 mg of nicotine) during the dose session and while in the CRU.
16. Receipt of an investigational product (including prescription medicines) as part of another clinical trial within 3 months prior to Day -1 or in the Follow-up period of another clinical trial at the time of Screening for this study.
17. Current use of a long-term prescription medicine and/or acute medicine (except antidepressant medication [Test Cohort Only] or HRT) deemed to pose a risk of interaction with the study drug, as assessed by the Investigator and in agreement with the Sponsor's Medical Monitor.
18. Use of any new prescription or non-prescription medications, including herbal and nutritional supplements, or OTC medications within 28 days of dosing and throughout the study. The patient may take paracetamol (less or equal to 4 g/day) or ibuprofen (less or equal to 1.6 g/day) for up to 4 hours prior to dosing. The Investigator and study team may review medication use on a case-by-case basis to determine if its use within 28 days prior to dosing would compromise patient safety or interfere with study procedures or data interpretation.
19. History of severe adverse reaction to any drug or history or sensitivity to serotonergic psychedelic drugs.
20. Persons of childbearing potential (POCBP) who are pregnant, lactating or planning to conceive, or who are sexually active with a partner capable of fathering a child, and not using a reliable method of contraception. A POCBP must have a negative serum pregnancy test at Screening, and a negative urine pregnancy test on Day -1. If a urine test cannot be confirmed as negative, a serum pregnancy test is required.
21. Donation of blood or plasma (more than 400 mL) within 3 months prior to dosing.
22. A phobia of needles or blood.
23. Unsuitable veins for venepuncture and/or cannulation.
24. Unlikely to cooperate with the requirements of the study, in the opinion of the Investigator or designee.
25. Objection by GP to patient entering the trial.

Date of first enrolment
13/12/2022

Date of final enrolment
03/08/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MAC Clinical Research Neuroscience Centre of Excellence
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Cybin UK Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
03/08/2024

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.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results	version 1	20/03/2024	10/06/2024	No	No