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Single ascending dose study with BPL-003 in healthy subjects

Submission date 24/01/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/01/2022	**Overall study status** Completed	
Last Edited 03/03/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
This is a study of 5-MEO-DMT (BPL-003; the study treatment) – a psychedelic substance that occurs naturally in some plants and animals. We're testing 5-MEO-DMT as an experimental new drug for treatment-resistant depression (TRD). There are existing treatments for depression, but they don't work well in all patients. About a third of patients (30–40%) have TRD, meaning their depression doesn't respond to at least 2 commonly available treatments. We hope the study treatment will give patients with TRD more treatment options.

Who can participate?
Healthy volunteers, aged 25–55 years who have never taken a psychedelic substance before

What does the study involve?
We'll give participants single doses of the study drug or placebo. This formulation of 5 MEO-DMT (the study treatment) has never been given to humans before, so we'll start with a small dose, and increase the dose as the study progresses. We will give single doses of study treatment intranasally, to find out: its side effects, blood levels, and psychedelic effects, and if it affects people's mood, feelings, and ability to read facial expressions. We'll also study how genes (pieces of DNA) affect the way the body responds to or handles the study treatment. Participants will take up to 2 weeks to finish the study. They'll make up to 5 outpatient visits, up to 2 video calls, and stay on the ward for 3 days and 2 nights. Outpatient visits will include 2 psychedelic preparation visits with an experienced psychedelic researcher in the week before their dosing visit. Participants will attend a screening visit during the 7 weeks before the study.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The study will take place at 1 centre in London (HMR)

When is the study starting and how long is it expected to run for?
November 2021 to January 2024

Who is funding the study?
A pharmaceutical company (Beckley Psytech Ltd) is funding the study.

Who is the main contact?
medinfo@beckleypsytech.com

Contact information

Type(s)
Public

Contact name
Dr . Beckley Psytech Ltd.

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
2021-006225-22

Integrated Research Application System (IRAS)
1004390

ClinicalTrials.gov (NCT)
NCT05347849

Protocol serial number
CRO code: 21-013

Study information

Scientific Title
A two-part phase 1, single ascending dose study to evaluate the safety, tolerability and pharmacokinetic profile of intranasal BPL-003 (5-Methoxy-N,N dimethyltryptamine Benzoate) in healthy subjects

Acronym
BPL-003-103

Study objectives
The study will evaluate safety, tolerability and PK profile of BPL-003 in healthy subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 20/01/2022, London - Brent Research Ethics Committee (80 London Road, Skipton House, London, SE1 6LH, UK; +44 (0)20 7104 8128, 020 7104 8137; brent.rec@hra.nhs.uk), REC ref: 21/LO/0834
2. Approved 21/01/2022, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 53791/0003/001-0001

The HRA has approved the deferral of the publication of trial details on 14/01/2022

Study design
First-in-man safety, pharmacokinetics and pharmacodynamics trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
The study will evaluate safety, tolerability and PK profile of BPL-003 in healthy subjects

Interventions
Drug/ BPL-003 arm: BPL-003
- A single dose of BPL-003 will be administered intranasally.
Placebo Comparator arm: Placebo
- A single dose of placebo will be administered intranasally.
Allocation: Randomized
Interventional Model: Sequential Assignment
Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Masking Description: Part A only

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
BPL-003 (5-Methoxy-N,N-dimethyltryptamine Benzoate)

Primary outcome(s)
Percentage of subjects with treatment emergent AEs (TEAES) [Time Frame: From screening through to the follow up visit, up to 65 days].

Key secondary outcome(s))
1. Peak plasma concentration (Cmax) [Time Frame: Day 1 (dosing day) and Day 2]
2. Time to reach Cmax (tmax) [Time Frame: Day 1 (dosing day) and Day 2]
3. Area under the plasma concentration- time curve [Time Frame: Day 1 (dosing day) and Day 2]

Completion date
19/01/2024

Eligibility

Key inclusion criteria
Medically healthy based on medical records and study specific assessments.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
55 years

Sex
All

Total final enrolment
62

Key exclusion criteria
Presence or history of severe adverse reaction to any drug or drug excipient.

Date of first enrolment
02/02/2022

Date of final enrolment
22/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Medicines Research (HMR)
Cumberland Avenue
Park Royal
London
United Kingdom
NW10 7EW

Sponsor information

Organisation
Beckley Psytech Ltd.

Funder(s)

Funder type
Industry

Funder Name
Beckley Psytech Ltd.

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 high 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?
Results article		14/04/2024	03/03/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes