ISRCTN10271810 https://doi.org/10.1186/ISRCTN10271810

# Single ascending dose study with BPL-003 in healthy subjects

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|---|---|---|
| **Submission date**<br>24/01/2022 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>26/01/2022 | **Overall study status**<br>Completed | |
| **Last Edited**<br>03/03/2025 | **Condition category**<br>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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### Type(s)
Principal Investigator

### Contact name
Dr Takahiro Yamamoto

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# Additional identifiers

### EudraCT/CTIS number
2021-006225-22

### IRAS number
1004390

### ClinicalTrials.gov number
NCT05347849

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Other

### Participant information sheet
Not available in web format

### 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

### Pharmaceutical study type(s)
Pharmacokinetic

### Phase
Phase I

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

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

### Secondary outcome measures
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]

### Overall study start date
01/11/2021

### Completion date
19/01/2024

## Eligibility

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

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Lower age limit
25 Years

**Upper age limit**
55 Years

**Sex**
Both

**Target number of participants**
56

**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**
England

United Kingdom

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

# Sponsor information

**Organisation**
Beckley Psytech Ltd.

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United Kingdom
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**Sponsor type**
Industry

**Website**
https://www.beckleypsytech.com

# Funder(s)

**Funder type**
Industry

**Funder Name**
Beckley Psytech Ltd.

# Results and Publications

**Publication and dissemination plan**
Publication of some trial details is deferred because of the high commercial sensitivity of this phase 1 study and the negligible benefit to the public of Phase I information. The sponsor does plan to report and disseminate the results of the study in the following ways: Internal Report, Conference Presentation, Publication on website and Submission to Regulatory Authorities.

**Intention to publish date**
14/04/2024

**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 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? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | | 14/04/2024 | 03/03/2025 | Yes | No |