Psilocybin in patients with fibromyalgia: EEG-measured brain biomarkers of action (Psilopain)

First published: 13/09/2022

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS48284

Study ID

48285

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Title: Psilocybin in patients with fibromyalgia syndrome: EEG-measured brain biomarkers of action (‘Psilopain’). Aims: To assess brain activity under psilocybin in a cohort of people with fibromyalgia. Design: A single arm, within-subjects study in 20 participants with fibromyalgia as defined by the American Rheumatological Society diagnostic criteria. Outcome Measures: The primary outcome is Lempel-Ziv complexity (LZc) of spontaneous brain activity recorded via EEG. Secondary outcomes will aim to capture broad aspects of the pain experience and related features through Magnetic Resonance Imaging (MRI), self-report measures, behavioural paradigms and qualitative interviews. Eligibility: Over 18 years of age, a good understanding of English language, registered with a primary care practice, no urgent clinical investigations or interventions for pain indicated. Procedure: Two dosing sessions, separated by four weeks with in-session EEG-recordings. Duration: This study will run for 27 months.

Study status

Ongoing

Research institutions and networks

Institutions

Imperial College London

United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Contact details

Study institution contact

Close James jclose@ic.ac.uk

Study contact

jclose@ic.ac.uk

Primary lead investigator

David Nutt

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/01/2022

Actual: 31/01/2022

Study start date

Planned: 15/08/2022

Actual: 15/08/2022

Data analysis start date

Planned: 02/10/2023

Date of final study report

Planned: 01/10/2024

Sources of funding

- Other

More details on funding

Philanthropy

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Imperial College London RGIT Sponsorship Number: 20HH6314,IRAS Project ID: 275349,REC reference: 21/PR/1008 URL: https://www.imperial.ac.uk/psychedelic-research-centre/trials/psilopain/

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Mechanistic Study

Main study objective:

The primary objective of this non-CTIMP (non-Clinical Trial of an Investigational Medicinal Product) early phase experimental medicine study is to utilise a within-subjects design to examine a candidate brain biomarker of increased plasticity (defined as the ability to change) under psilocybin, Lempel-Ziv complexity (LZc).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Within-subjects, single arm study

Study drug and medical condition

Medicinal product name, other

Psilocybin

Medical condition to be studied

Fibromyalgia

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

20

Study design details

Outcomes

1) Lempel-Ziv complexity (LZc) 2) The Brief Experiential Avoidance Questionnaire (BEAQ), 1) Structural and functional magnetic resonance imaging 2) Patient reported outcome measures 3) Physiology: Heart rate, body temperature, accelerometry 4) Qualitative interviews

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Data analysis plan

With an assumption of high co-linearity between core outcomes we will explore data reduction approaches (e.g. factor or principal component analyses or canonical correlation analysis) to investigate key contrasts. Two tailed tests will be performed if findings are not aligned with prior hypotheses. Due to prior hypotheses on directionality, one tailed t-tests will be performed when appropriate. Multiple comparisons corrections and Bayesian analyses will be

performed where deemed appropriate.

Data management

ENCePP Seal

> The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No