ISRCTN14426797 https://doi.org/10.1186/ISRCTN14426797

Psilocybin for depression

Submission date	Recruitment status	[ ] Prospectively registered
30/03/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/07/2015	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/01/2021	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Depression affects people in different ways and can cause a wide variety of symptoms. They range from lasting feelings of sadness and hopelessness (low mood), to feeling very tearful at unexpected moments (emotional lability). Many people with depression also have symptoms of anxiety. Treatment for depression involves either medication or talking treatments, but these do not work for everybody because some people have depression that is treatment-resistant. Psilocybin is a hallucinogenic drug that comes from what is often called 'magic mushrooms'. The drug can put some people in a euphoric mood for a number of hours and reduce anxiety. Psilocybin has been given to healthy volunteers and to patients suffering from Obsessive Compulsive Disorder (OCD) and anxiety before with positive results, but it has not been tested in depression. The aim of this initial study is to investigate how this drug works on patients with treatment-resistant depression. We also want to find out which dose gives predictable results in improving peoples' mood.

Who can participate?
Patients referred from local London psychiatric teams.

What does the study involve?
The potential psychological effects of psilocybin are fully described to all patients before they sign up for the study. Participants are made to feel very prepared for their experience before taking the drug and are taught ways to relax to reduce anxiety and promote a positive drug experience. Patients receive a low dose in the first session so that they have a first impression of the drug experience before moving on to a higher dose. People can respond to the drug very differently from one another and some may not want to take the higher dose. A positive environment is created during the study so that participants feel relaxed and don't feel worried. The study team has a psychiatrist and psychotherapist and all dosing sessions are supervised by a medical doctor. Follow-up meetings take place after each dosing session and any bad feelings experienced by participants will be managed by the study psychiatrist, GPs and/or community mental health professionals.

What are the possible benefits and risks of participating?
Bad side effects are rare when psilocybin is taken by healthy volunteers but they may be more likely in vulnerable patients such as those with depression. Risks include anxiety, 'bad trips' (dysphoria) and rarer psychotic responses. We will minimise risks by excluding patients

experiencing psychotic symptoms at the time of the study, or those who have a personal/family history of psychosis. The occurrence of negative feelings experienced by people taking psilocybin depends on the dose amount so the maximum dose we give is considered moderate in healthy volunteers.

Where is the study run from?
Imperial Clinical Research Facility, Hammersmith Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2015 to December 2015

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr R Carhart-Harris (UK)

Contact information

Type(s)
Scientific

Contact name
Dr Robin Carhart-Harris

Contact details
Burlington Danes Building, Du Cane Rd
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Additional identifiers

EudraCT/CTIS number
2013-003196-35

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 7

Study information

Scientific Title
Assessing the subjective intensity of oral PSILOcybin in patients with treatment-resistant DEPression: a PILOT study

Acronym

PSILODEP-PILOT

Study objectives
Psilocybin will reduce symptoms of depression in patients diagnosed with treatment-resistant depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES London West London, 03/09/2014, ref: 13/LO/1224

Study design
Open label design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Major depression

Interventions
Two doses of psilocybin 10mg and 25mg per so, separated by one week

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Psilocybin

Primary outcome measure
Quick Inventory of Depressive Symptoms (QIDS) questionnaire at start of trial, then one day and one week post-psilocybin. QIDS is a self-report measure of depressive symptoms

Secondary outcome measures
1. Beck Depression Inventory (BDI) questionnaire
2. Hamilton Depression Rating Scale (HAM-D) questionnaire
3. Montgomery–Åsberg Depression Rating Scale (MADRS) questionnaire

Overall study start date
21/04/2015

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Major depression of a moderate to severe degree (17+ on the 21-item HAM-D)
2. No improvement despite two courses of antidepressant treatment for adequate duration (6 weeks minimum) within current episode
3. No magnetic resonance imaging (MRI) contraindications

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Current or previously diagnosed psychotic disorder
2. Immediate family member with a diagnosed psychotic disorder
3. Medically significant condition rendering unsuitability for the study (e.g., diabetes, epilepsy, severe cardiovascular disease, hepatic or renal failure etc)
4. History of suicide attempts
5. History of mania
6. Blood or needle phobia
7. Positive pregnancy test at screening or during the study
8. Current drug or alcohol dependence
9. Allergy to gelatine or lactose
10. Lack of appropriate use of contraception
11. Breastfeeding

Date of first enrolment
21/04/2015

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial Clinical Research Facility
Hammersmith Hospital
London
United Kingdom
W10 5NA

Sponsor information

Organisation
Imperial College London

Sponsor details
Burlington Danes Building
Du Cane Rd
London
England
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Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We intend to analyse the results with a view to publication in peer-reviewed scientific press. The first study report will be prepared after 01/12/2015.

Intention to publish date
01/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2016		Yes	No
Results article	results	17/01/2018		Yes	No
Results article	results	01/11/2018		Yes	No
Results article	results	01/02/2020	12/01/2021	Yes	No
HRA research summary			28/06/2023	No	No