Clinical trial results:
Assessing the subjective intensity of oral psilocybin in patients with treatment-resistant depression: A Pilot Study

Summary

EudraCT number	2013-003196-35
Trial protocol	GB
Global end of trial date	27 September 2016

Results information

Result version number	v1 (current)
This version publication date	03 January 2020
First version publication date	03 January 2020

Trial information

Trial identification

Sponsor protocol code	13HH0762

Additional study identifiers

ISRCTN number	ISRCTN14426797
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	REC: 13/LO/1224 , MRC: MR/J00460X/1

Notes:

Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	Exhibition Road, London, United Kingdom, SW7 2AZ
Public contact	Carhart-Harris, Robin, Imperial College London, 44 02075946550, r.carhart-harris@imperial.ac.uk
Scientific contact	Carhart-Harris, Robin, Imperial College London, 44 02075946550, r.carhart-harris@imperial.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 July 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 September 2016
Global end of trial reached?	Yes
Global end of trial date	27 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

How sensitive are patients with depression to the subjective effects of psilocybin?

Protection of trial subjects:

24-hour contact number to study psychiatrist

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 January 2015
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Most recruitment happened through self-referrals and also through the Clinical Research Network. Patients first had a telephone screening and if they appeared suitable came in for a face-to-face screening. 120 subjects applied, 74 were telephone screened, 29 did a face-to-face screening. 20 were enrolled, 19 completed.

Pre-assignment

Screening details:

Inclusion: Major depression moderate-severe (HAMD 17+) and no response to at least 2 full courses of treatment within current episode. Exclusion: history of psychosis and family members with psychosis, medically significant conditions, history of suicide attempts, needle and blood phobia, pregnancy at screening or during study, current addiction.

Pre-assignment period milestones

Number of subjects started	20
Number of subjects completed	20

Period 1

Period 1 title	Baseline fMRI and Prep
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

NA - open label safety pilot study

Arms

Arm title	All patients - baseline

Arm description:

All patients were prepped for psilocybin sessions, did baseline questionnaires and fMRI.

Arm type	No intervention, run-in period
Investigational medicinal product name	No intervention
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Other use

Dosage and administration details:

No intervention, run-in, preparation period

Number of subjects in period 1	All patients - baseline
Started	20
Completed	20

Period 2

Period 2 title	Treatment
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

NA

Arms

Arm title	All patients - treatment

Arm description:

Patients receive two doses of psilocybin, 1 week apart

Arm type	Experimental
Investigational medicinal product name	Psilocybin 10mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

2x 5mg capsules = 10mg psilocybin

Investigational medicinal product name	Psilocybin 25mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

5x 5mg capsules = 25mg

Number of subjects in period 2	All patients - treatment
Started	20
10mg psilocybin session	20
25mg psilocybin session	20
Completed	20

Period 3	
Period 3 title	Post-treatment follow-ups
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded
Blinding implementation details: NA	

Arms	
Arm title	All patients
Arm description: fmRI and remote follow-ups up to 6 months	
Arm type	all, no arms
No investigational medicinal product assigned in this arm	

Number of subjects in period 3	All patients
Started	20
Completed	19
Not completed	1
Adverse event, non-fatal	1

Baseline characteristics

Reporting groups	
Reporting group title	Baseline fMRI and Prep

Reporting group description: -

Reporting group values	Baseline fMRI and Prep	Total	
Number of subjects	20	20	
Age categorical Units: Subjects			
Adults (18-64 years)	20	20	
Gender categorical Units: Subjects			
Female	6	6	
Male	14	14	

End points

End points reporting groups

Reporting group title	All patients - baseline
Reporting group description:	
All patients were prepped for psilocybin sessions, did baseline questionnaires and fMRI.	
Reporting group title	All patients - treatment
Reporting group description:	
Patients receive two doses of psilocybin, 1 week apart	
Reporting group title	All patients
Reporting group description:	
fmRI and remote follow-ups up to 6 months	

Primary: Quick Inventory of Depressive Symptomatology (QIDS-16)

End point title	Quick Inventory of Depressive Symptomatology (QIDS-16)
End point description:	

End point type	Primary
End point timeframe:	
Baseline vs 5 weeks post treatment	

End point values	All patients - baseline	All patients		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: QIDS score	19	10		

Statistical analyses

Statistical analysis title	two-tailed paired t-test (Bonferroni corrected)
Comparison groups	All patients - baseline v All patients
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	t-test, 2-sided

Secondary: Beck Depression Inventory (BDI)

End point title	Beck Depression Inventory (BDI)
End point description:	

End point type	Secondary
End point timeframe: Baseline vs 1 week post-treatment	

End point values	All patients - baseline	All patients		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: BDI score	35	12		

Statistical analyses

Statistical analysis title	two-tailed paired t-test (Bonferroni corrected)
Comparison groups	All patients - baseline v All patients
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	t-test, 2-sided

Secondary: State Trait Anxiety Inventory - Trait (STAI-T)

End point title	State Trait Anxiety Inventory - Trait (STAI-T)
End point description:	

End point type	Secondary
End point timeframe: Baseline vs 1 week post treatment	

End point values	All patients - baseline	All patients		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: STAI-T units	69	45		

Statistical analyses

Statistical analysis title	two-tailed paired t-test (Bonferroni corrected)
Comparison groups	All patients v All patients - baseline

Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	t-test, 2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: just before, during and few days after psilocybin sessions	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	NK
Reporting groups	
Reporting group title	All patients

Reporting group description: -

Serious adverse events	All patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	All patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 20 (100.00%)		
General disorders and administration site conditions			
Headache	Additional description: Lasting 1-2 days		
subjects affected / exposed	8 / 20 (40.00%)		
occurrences (all)	8		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	5 / 20 (25.00%)		
occurrences (all)	5		
Psychiatric disorders			
Anxiety	Additional description: Transient anxiety lasting minutes		
subjects affected / exposed	15 / 20 (75.00%)		
occurrences (all)	15		
Paranoia	Additional description: Transient paranoia		

subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Open label safety study, no control group.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/29119217

http://www.ncbi.nlm.nih.gov/pubmed/27210031