

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of efficacy and safety of *Psilocybe cubensis* on depression and PTSD symptoms of veterans; a randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim

pharmacologic evaluation of the alkaloids extracted from *psilocybe cubensis* on symptoms of Post-traumatic stress disorder (PTSD)

Design

Purification of the alkaloids will be performed through a common method designed for alkaloids specifically. A chromatographic method (HPLC) will be used to detect the amount of psilocybin. Then, we formulate solid capsule dosage forms with 20 milligrams of psilocybin in a capsule. A randomized, double-blind, placebo-controlled clinical trial with treatment (the alkaloids) group and 68 sample size. 1) The treatment group will receive alkaloids and the common antidepressants (SSRIs or SNRIs), while 2) the placebo group will take fried bread and SSRIs for 6 weeks.

Settings and conduct

The study was conducted in the outpatient at 505 hospital. Demographic characteristics of patients are registered at the start of the study. Evaluations include HAM-D, PCL-V, and BAI scores are recorded on days 0, 28, and 42

Participants/Inclusion and exclusion criteria

veterans with a diagnosis of Post-traumatic stress disorder (PTSD)

Intervention groups

1) Control group: will receive a single dose of placebo capsules, with the exact size, color, and appearance were filled with fried bread at the first of the study 2) treatment group: will receive a single dose of 20 milligrams of alkaloids extracted from the *psilocybe* mushroom at the first of the study

Main outcome variables

depressed mood; Feelings of guilt; Suicide; Insomnia (early, middle, and late insomnia); Work and interests; Psychomotor retardation; Psychomotor agitation; Anxiety, psychic; Anxiety, somatic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170311033004N4**

Registration date: **2022-06-28, 1401/04/07**

Registration timing: **prospective**

Last update: **2022-06-28, 1401/04/07**

Update count: **0**

Registration date

2022-06-28, 1401/04/07

Registrant information

Name

Ali Razmi

Name of organization / entity

Academic Center for Education, Culture and Research

Country

Iran (Islamic Republic of)

Phone

+98 26 3476 4015

Email address

arazmi@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Evaluation of efficacy and safety of Psilocybe cubensis on depression and PTSD symptoms of veterans; a randomized, double-blind, placebo-controlled trial
Public title	Evaluation of efficacy and safety of Psilocybe mushroom on depression and post-traumatic stress disorder symptoms in veterans
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	patients with PTSD diagnosis moderate to severe depression male aged 45-75 years without any previous diagnosis of other mental disorders such as without any previous diagnosis of diabetes or CV disorders without diagnosis of the other mental disorders taking antidepressants SSRIs or SNRIs not hospitalized
Exclusion criteria:	they have a diagnosis of psychosis suicide attempting taking antidepressants except for SSRIs and SNRIs or electroconvulsive therapy follow up interrupting sensitivity to the mushroom emerging adverse effects including fever, GI and heart diseases hospitalization
Age	From 45 years old to 75 years old
Gender	Male
Phase	2
Groups that have been masked	- Participant - Care provider
Sample size	Target sample size: 68
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization will be performed through block randomization (block of four). In Excel, we would arrange the Treatment and Control values systematically and then add a column with a block number. The third column would be our random numbers. Here is what it would look like. Then, we sort the numbers, by block and by random number within block.
Blinding (investigator's opinion)	Double blinded
Blinding description	Blinding and randomization will be carried out by an independent person unrelated to the study, while the investigator will administrate capsules and will assess the patients. Capsules will be packed and numbered serially using numbers generated by random number tables. They are the same in appearance, size, and color.
Placebo	Used
Assignment	Parallel

Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	دانشگاه علوم پزشکی ارتش جمهوری اسلامی ایران
Street address	Chamran highway
City	Tehran
Province	Tehran
Postal code	1411718541
Approval date	2022-06-19, 1401/03/29
Ethics committee reference number	IR.AJAUMS.REC.1401.024
Health conditions studied	
<u>1</u>	
Description of health condition studied	Posttraumatic stress disorder (PTSD)
ICD-10 code	F43.1
ICD-10 code description	Post-traumatic stress disorder (PTSD)
Primary outcomes	
<u>1</u>	
Description	Anhedonia, depressed mood, change in appetite, sleep, BAI score, and suicidal ideations
Timepoint	Days 0, 28 and 42
Method of measurement	BAI, HDRS and PCL-V questionnaires
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: Psilocybe cubensis alkaloids: The alkaloids purified through routine methods for alkaloids purifications. Then a semi-automatic capsule filler was used to fill the the capsules, prepared in an opaque

plastic container. Patients received powder capsules (equivalent 20 mg alkaloids), standardized to reference.

Category

Treatment - Drugs

2

Description

Control group: Control group: Placebo capsules, with the exact size, color, and appearance, were filled with fried bread.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

AJA 505 hospital

Full name of responsible person

Mohammad Reza Ghasemzadeh

Street address

Artesh highway, Oshan Blvd

City

Tehran

Province

Tehran

Postal code

1956944141

Phone

+98 21 2248 1806

Email

m.rezaghasemzadeh@yahoo.com

Web page address

<https://bima505.ajaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Ali Razmi

Street address

Enghelab street, facing University of Tehran, central office

City

Tehran

Province

Tehran

Postal code

436414155

Phone

+98 21 6648 8515

Fax

+98 21 6648 8518

Email

secretariat@acecr.ac.ir

Web page address

<http://acecr.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iranian academic center for education culture and research

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Ali Razmi

Position

Assistant preofessor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Institute of medicinal plants, Alborz science and technology park, Kamalshahr

City

Karaj

Province

Alborz

Postal code

3365166571

Phone

+98 26 3476 4015

Fax

+98 26 3476 4021

Email

arazmi@alumnus.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Ali Razmi

Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Kamalshahr, Jahad daneshgahi research complex
City
Kamalshahr
Province
Alborz
Postal code
3365166571
Phone
+98 26 3476 4010
Fax
+98 26 3476 4021
Email
arazmi@alumnus.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Ali Razmi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Kamalshahr, Jahad daneshgahi research complex
City
Kamalshahr
Province
Alborz
Postal code

3365166571
Phone
+98 26 3476 4010
Fax
+98 26 3476 4021
Email
arazmi@alumnus.tums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

demographic data and questionnaire final scores will be shared.

When the data will become available and for how long

after publication

To whom data/document is available

Researchers from all the medical universities

Under which criteria data/document could be used

The data can be used results in review articles.

From where data/document is obtainable

The data is available by calling Dr Ali Razmi; assistant professor at ACECR. email: arazmi@alumnus.tums.ac.ir
Tel: 00989123945632

What processes are involved for a request to access data/document

The request should be sent to the email.

Comments