Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the efficacy of Pasipay drop (Passiflora incarnata) in the treatment of minor depressive disorder

Protocol summary

Study aim
The aim of this study is evaluating the effectiveness of hydroalcoholic extract of passiflora incarnata in the treatment of major depressive disorder.

Design
This is a randomized, double-blind, placebo-controlled clinical trial The total sample size is 70 patients

Settings and conduct
This study will be conducted in Emam Reza clinic in Shiraz This study is triple blinded. Participants, care provider, outcome assessor, and analysts will blind

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged at least 18 non-inclusion: pregnancy; breastfeeding; serious and unstable disease; opium addiction; drug or alcohol abuse or dependency; the history of seizure; patients at risk of suicidal attempt; patients with a history of suicide

Intervention groups
Patients in the intervention group will receive 40 drops of hydroalcoholic standard extract of passiflora incarnata orally daily for 8 weeks and placebo group will receive 40 drops of placebo orally daily

Main outcome variables
patients will follow at baseline and with 2 week interval up to the 8 weeks using HAM-D 17 questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141227020441N8**
Registration date: **2020-02-13, 1398/11/24**
Registration timing: **prospective**

Last update: **2020-02-13, 1398/11/24**
Update count: **0**

Registration date
2020-02-13, 1398/11/24

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-20, 1398/12/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the efficacy of Pasipay drop (Passiflora incarnata) in the treatment of minor depressive disorder

Public title
The efficacy of Pasipay drop (Passiflora incarnata) in the treatment of minor depressive disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Outpatient depress patients HAM-D score ≥18 18 years old or more without other psychiatric disorder Patients

should not have been received psychotropic medications at least 4 weeks before study entry

Exclusion criteria:

pregnancy planning for pregnancy breastfeeding serious and unstable disease opium addiction drug or alcohol abuse or dependency history of seizure patients at risk of suicidal attempt history of suicide

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is conducted by the table of random numbers

Blinding (investigator's opinion)

Triple blinded

Blinding description

The triple-blind trial is planned in such a way that the study subjects, observers, and analyzers do not know who is in which group. The patient is identified by a code that is inserted in the envelope, and elsewhere it is clear whether this number is related to the drug or the placebo

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand blvd., Shiraz, Iran.

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Province

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Postal code

71345-1978

Approval date

2019-08-31, 1398/06/09

Ethics committee reference number

IR.SUMS.REC.1398.752

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

Primary outcomes

1

Description

Score of depression by HAM-D17 questionnaire with score<16

Timepoint

At baseline and at the weeks 2, 4, 6 and 8

Method of measurement

HAM-D17 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 drops hydroalcoholic extract of passiflora incarnata orally daily for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: 30 drops placebo orally daily for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza clinic

Full name of responsible person

Farzaneh Froughinia

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
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
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available