

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison effect of Ziziphi jujube and Melissa Officinale extract with Escitalopram on the treatment of adulthood depression

Protocol summary

Study aim

comparing the effect of hydroalcoholic extract of combined plants of Ziziphi jujube and Melissa officinale with escitalopram in the treatment of mild to moderate adult depression

Design

In this non-blinded randomized parallel clinical trial, 80 Patients are allocated randomly with simple sequential allocation in one of the two groups (herbal extract or escitaloperam) and receive the intervention of that group.

Settings and conduct

Adult patients older than 18 years old suffering from mild to moderate depression allocated in one of two groups. The first group will receive a combined alcoholic extract of Ziziphi jujube and Melissa officinale with a dose of 600 milligrams per day and prescribed with 10 milligrams of escitalopram every morning with for three weeks. In the second group 10 milligrams of escitalopram tablet, will be prescribed every morning same as the first group. At the beginning and 3 and 6 weeks later patients visit and severity of depression and rate of improvement checked by Hamilton questionnaire and will be recorded

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult patients older than 18 years old with mild to moderate depression, having informed consent form Exclusion criteria: Bipolar disorder, patients with cardiovascular or hepatic disease, history of herbal or medicinal allergy ,pregnant women

Intervention groups

Intervention group : Combined alcoholic extract of Ziziphi jujube and Melissa officinale with a dose of 600 milligrams per day prepared in form of a capsule and prescribed with 10 milligrams of escitalopram tablet every morning with one glass of water for three weeks. Control group: A tablet of escitalopram with a dose of 10 milligrams will be prescribed every morning with one glass of water for three weeks.

Main outcome variables

improvement of depression symptoms according to Hamilton questionnaire and patient report

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081011001323N28**

Registration date: **2021-10-22, 1400/07/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-22, 1400/07/30**

Update count: **0**

Registration date

2021-10-22, 1400/07/30

Registrant information

Name

Sadrollah Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3334 6070

Email address

dr.mehrabi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-21, 1400/05/30

Expected recruitment end date

2022-08-21, 1401/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of Ziziphi jujube and Melissa Officinale extract with Escitalopram on the treatment of adulthood depression

Public title

Comparison effect of Ziziphi jujube and Melissa Officinale extract with Escitalopram on the treatment of depression

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult patients(older than 18 years old) Suffering from mild to moderate depression Having informed consent form

Exclusion criteria:

Suffering from bipolar disorder Patients with acute psychosis Patients with cardiovascular disease or hepatic function impairment Patients with any history of allergy to chemical or herbal drugs Pregnant women

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are allocated randomly with simple random allocation method by use of random number table to one of each group combined herbal extract or escitalopram) and received the intervention of that group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Mottahari srteet, Yasuj, Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741414

Approval date

2021-08-17, 1400/05/26

Ethics committee reference number

IR.YUMS.REC.1400.128

Health conditions studied**1****Description of health condition studied**

moderate depression

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

Primary outcomes**1****Description**

Improvement of depression symptoms

Timepoint

Before start of treatment,3 and 6 weeks later

Method of measurement

According to Hamilton questionnaire

Secondary outcomes**1****Description**

Evaluating drug reactions

Timepoint

During treatment and 3 and 6 weeks next

Method of measurement

According to patient reports and physician examination

Intervention groups**1****Description**

Intervention group: Combined alcoholic extract of Ziziphi jujube and Melissa officinale with a dose of 600 milligrams per day prepared in form of capsule and prescribed with 10 milligrams of escitalopram tablet every morning with one glass of water for three weeks.

Category

Treatment - Drugs

2

Description

Control group: Escitalopram tablet in a dose of 10 milligrams of prescribed every morning with one glass of water for three weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofateh clinic of Yasuj

Full name of responsible person

Sadrolleh Mehrabi

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Shahid Mofateh clinic, Montazeri Street, Yasuj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Ali Mousavizadeh

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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

Yasuj 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

Contact

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Saied Razmeh

Position

Assistant professor, Neurology Department, Yasuj University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Full name of responsible person

Sadrollah Mehrabi

Position

Professor, Chairman of Urology Department, Yasuj University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available