

# 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

##### Street address

Shahid Mofateh clinic, Montazeri Street, Yasuj

##### City

Yasuj

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Kohgilouyeh-va-Boyrahmad

##### Postal code

7591741417

##### Phone

+98 74 3322 1812

##### Email

sadrollahm@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yasuj University of Medical Sciences

##### Full name of responsible person

Ali Mousavizadeh

##### Street address

Deputy of research, Yasuj University of Medical Sciences,, Motahari St

##### City

Yasuj

##### Province

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##### Phone

+98 74 3334 6074

##### Email

health.epid@gmail.com

##### 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

##### Street address

Shahid Mofateh clinic, Montazeri street, Yasuj, Iran

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Yasuj University of Medical Sciences

##### 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**

Yasouj University of Medical Sciences

**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**

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**Email**

dr.mehrabi@yums.ac.ir

**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