

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparison of effect between Ziziphus jujube fruit and benzodiazepines in patients with depression and anxiety disorders treated with selective serotonin reuptake inhibitors

#### Protocol summary

##### Study aim

Determining the effects of jujube fruit compared to benzodiazepines in patients with depression and anxiety disorder treated with SSRI

##### Design

Randomized clinical trial with a control group with parallel groups including 25 people in each group, one blind, randomized using block method.

##### Settings and conduct

This study will be conducted in the specialized psychiatric clinic of Bahlul Gonabadi Hospital. 50 patients with anxiety and depression disorders who meet the conditions to enter the study will be randomly assigned to two intervention and control groups. This study will be blinded to the analyst.

##### Participants/Inclusion and exclusion criteria

Entry criteria: Referees to the specialized psychiatric clinic of Bohlool Hospital in Gonabad city, who have been diagnosed with anxiety and depression based on DSM-V criteria, aged 18 to 65 years, patients who are candidates for treatment with SSRIs and benzodiazepines, having written informed consent To participate in the research. Exclusion criteria: history of sensitivity to jujube fruit consumption, consumption of jujube or other herbal medicines during the last 4 weeks before starting the study, history of addiction, pregnancy or intention to become pregnant, breastfeeding, history of suffering from other psychiatric disorders.

##### Intervention groups

The test and control group includes patients with anxiety and depression disorders. The test group is treated for one month with standard drug (SSRI) + jujube fruit powder, one 15 gram sachet daily, and the control group is treated with SSRI + benzodiazepine

##### Main outcome variables

Beck's anxiety score, Beck's Depression Score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200418047116N4**

Registration date: **2023-10-09, 1402/07/17**

Registration timing: **prospective**

Last update: **2023-10-09, 1402/07/17**

Update count: **0**

##### Registration date

2023-10-09, 1402/07/17

##### Registrant information

##### Name

Negar Shafaei bajestani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5723 6833

##### Email address

shafaei.n@gmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-22, 1402/09/01

##### Expected recruitment end date

2024-08-22, 1403/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of effect between Ziziphus jujube fruit and benzodiazepines in patients with depression and anxiety disorders treated with selective serotonin reuptake inhibitors

## Public title

The effect of Ziziphus jujube in the treatment of anxiety and depression

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Referees to the specialized psychiatric clinic of Bohlool Hospital in Gonabad city who have been diagnosed with anxiety and depression disorders based on DSM-V criteria. Candidate patients for treatment with SSRI and benzodiazepines, Having written informed consent to participate in the study Age 18 to 65 years

### Exclusion criteria:

History of sensitivity to jujube fruit consumption (based on the individual's own report) History of addiction Pregnancy or intention to become pregnant History of other psychiatric disorders Breastfeeding Taking jujube or other herbal medicines during the last 4 weeks before the start of the study Contraindications for benzodiazepine or SSRI administration Mental retardation Taking drugs that interfere with study drugs

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Data analyser

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In the current study, patients suffering from anxiety and depression referring to the psychiatric clinic of Allameh Bahloul Gonabadi Hospital are selected using available sampling method. In order to assign the patients to two intervention and control groups, he used the method of quadruple permutation blocks in such a way that first six possible states of the blocks. Then people are assigned to the control group (A) and the intervention group (B) based on the block corresponding to the selected number. It will continue until the end of the sample volume

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study, blinding is done only for the analyst in such a way that two treatment groups with two codes A and B will be determined in the software, and the analyst will not know the nature of the treatment codes.

## Placebo

Not used

## Assignment

Parallel

## Other design features

In this study, when obtaining written consent, the possibility of complications for the patients (whether they are in the test group or the control group) is explained, and the patients are requested to report to the project manager or the doctor in case of any complications. Notify your specialist. In case of complications, the patient can be excluded from the study. Then, depending on the type of complication and with the opinion of their specialist doctor, their symptoms are treated. The patients have a close relationship with their doctor and the project manager throughout the study period.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Gonabad University of Medical Science

##### Street address

Gonabad - Asian Roadside - Gonabad University of Medical Sciences

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

#### Approval date

2023-01-25, 1401/11/05

#### Ethics committee reference number

IR.GMU.REC.1401.161

## Health conditions studied

### 1

#### Description of health condition studied

anxiety

#### ICD-10 code

F41.9

#### ICD-10 code description

Anxiety disorder, unspecified

### 2

#### Description of health condition studied

depression

#### ICD-10 code

F32.9

#### ICD-10 code description

Major depressive disorder, single episode, unspecified

## Primary outcomes

### 1

#### Description

Anxiety scores in the Beck questionnaire

#### Timepoint

Before the intervention, one month and three months after the intervention

#### Method of measurement

Beck anxiety questionnaire

## Secondary outcomes

### 1

#### Description

Severity of Illness

#### Timepoint

One month and three months after the intervention

#### Method of measurement

Global Clinical Perception Questionnaire - Severity of Illness

### 2

#### Description

Drowsiness check

#### Timepoint

One month and three months after the intervention

#### Method of measurement

Complications survey questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: Jujube powder purchased from Shayna, a 15 gram sachet once a day, will be added to the main treatment (SSRI) for one month.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: treated with a routine drug regimen including SSRI and BZD for one month.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Specialized Psychiatry Clinic of Bohlool Gonabadi Hospital

##### Full name of responsible person

Negar Shafaei Bajestani

#### Street address

Nurse St., Specialized Psychiatry Clinic of Allameh Bohlool Gonabadi Hospital

#### City

Gonabad

#### Province

Razavi Khorasan

#### Postal code

9691793718

#### Phone

+98 51 5723 6833

#### Email

Shafaei.n@gmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Full name of responsible person

Dr. Leila Sadegh Moghadam

##### Street address

Dr.Mehdizade Blvd.

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

##### Phone

+98 51 5722 3028

##### Email

info@gmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

##### Full name of responsible person

Negar Shafaei Bajestani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Allameh Bohlool Gonabadi Hospital, Vahdat Blvd.,Saadi St.

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691797852

**Phone**

+98 51 5723 6833

**Email**

negar.shafaei89@gmail.com

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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**Postal code**

9691797852

**Phone**

+98 51 5723 6833

**Email**

negar.shafaei89@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Negar Shafaei Bajestani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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**Phone**

+98 51 5723 6833

**Email**

negar.shafaei89@gmail.com

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

Gonabad University of Medical Sciences

**Full name of responsible person**

Negar Shafaei Bajestani

**Position****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**

Undecided - It is not yet known if there will be 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data can be shared after patients are made unidentifiable.

**When the data will become available and for how long**

Data can be accessible 6 months after results are published.

**To whom data/document is available**

The researchers in university and other scientific institutes.

**Under which criteria data/document could be used**

Help in managing of patients.

**From where data/document is obtainable**

Data can be accessible through sending an email to the corresponding author. Negar Shafaei-Bajestani  
negar.shafaei89@gmail.com

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

after sending a request email to the corresponding author, data will be sent in 1 month.

**Comments**