

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of adding oral vitamin C to standard treatment of major depressive disorder

Protocol summary

Registration timing: **prospective**

Study aim

Determining the effect of adding oral vitamin C to the standard treatment of major depressive disorder in patients referred to the clinics of Shahid Sadoughi University of Medical Sciences, Yazd

Last update: **2021-07-12, 1400/04/21**

Update count: **0**

Registration date

2021-07-12, 1400/04/21

Design

This clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 is performed on 90 patients with major depressive disorder. For randomization, a simple random method is used using the card selection method from inside the box.

Registrant information

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Name of organization / entity

Isfahan University of Medical Sciences

Country

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Settings and conduct

This clinical trial study was performed in 1400 and 1401 in Shahid Sadoughi Hospital in Yazd. The study was conducted as a double-blind study and patients and the person evaluating the outcome of treatment were unaware of the type of drug received.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

In this study, patients with major depressive disorder who are at least 18 years old, have a minimum literacy and have the ability and conditions to answer questions are included in the study. Addicted patients, patients with underlying diseases, patients who have changed their diet in the past month are not included in the study.

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-09-22, 1401/06/31

Intervention groups

Patients in the intervention group will be given 500 mg of vitamin C tablets twice a day and in the control group, placebo tablets will be prescribed in the same way for 2 months.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

improve the symptoms of major depressive disorder

Trial completion date

empty

General information

Scientific title

The effect of adding oral vitamin C to standard treatment of major depressive disorder

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N56**

Registration date: **2021-07-12, 1400/04/21**

Public title

The effect of adding vitamin C tablets to the treatment regimen of patients with major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having major depressive disorder Patient consent to participate in the study Minimum literacy Has a high level of consciousness Has suitable conditions for completing the questionnaire

Exclusion criteria:

Drug addiction Underlying diseases such as diabetes, cardiovascular, lung, cancer Major changes in diet in recent months Verbal and auditory problems in which they are unable to communicate Antioxidant use one month before enrollment,

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are distributed in two groups by simple random allocation method. To do this, the letter A is written on 45 cards and the letter B is written on 45 cards, and all the cards are placed in a box and mixed well. Patients take a card out of the box when they visit and the patient is assigned to the intervention or control group according to what is written on the card.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is done in two blinds. Patients and the person evaluating the outcome of treatment are unaware of the type of medication used by patients. Drugs are prepared in similar packages and coded by the project manager and are provided to patients for consumption.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadughi University of

Medical Sciences

Street address

Shohadaye Gomnam street

City

Isfahan

Province

Isfahan

Postal code

8434193474

Approval date

2021-02-09, 1399/11/21

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.291

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Intensity of Major Depressive Disorder

Timepoint

Before the intervention, one month and two months after the start of the intervention

Method of measurement

Using the Hamilton Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Daily administration of 500 mg of vitamin C tablets twice a day, in addition to routine treatment of major depressive disorder for two months.

Category

Treatment - Drugs

2

Description

Control group: Prescribe a placebo similar to 500 mg vitamin C tablets twice a day for two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatric Clinic of Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Mahsa Mahdavi

Street address

Shohadaye Gomnam street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Mohamad Nadi Sakhvidi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Reza Bidaki

Position

Associate professor

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Specialist

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ali Mehrabi

Position

Statistical Consultant

Latest degree

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Other areas of specialty/work

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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

The project belongs to a government organization and it is not possible to share it.

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