

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of niacin addition to Escitalopram in patients with depression

Protocol summary

Study aim

Evaluation of niacin addition to Escitalopram in patients with depression

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 1 on 66 patients. Online website (<https://www.sealedenvelope.com>) will be used for randomization.

Settings and conduct

The study is conducted in a double-blind manner at the neuropsychiatric clinic of Golestan Hospital, Ahvaz. The patients are divided into two groups of 33 people, they are subjected to S-citalopram with niacin or S-citalopram with placebo, and after eight weeks, its effect on back pain and its complications are investigated in the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: score 18 to 11 in the Hamilton depression test, diagnosis of mild and moderate depression based on structured interview based on DSM-5 and Hamilton index, age 10 to 68 years. Exclusion criteria: In case of electric shock in the last two months, thyroid diseases, psychotic disorder, pregnant mothers, severe depression, allergy to niacin.

Intervention groups

Intervention group: The intervention group (33 people) will receive niacin supplement in addition to citalopram as an anti-depressant drug. Niacin supplementation starts with half a gram and increases half a gram every 0 weeks. Control group: The control group (33 people) will receive a placebo in addition to S-citalopram for eight weeks. The evaluation will be done by a psychiatrist. Escitalopram drug started with 6 mg daily and reached 18 mg in the second week.

Main outcome variables

Depression score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231207060286N1**

Registration date: **2023-12-17, 1402/09/26**

Registration timing: **prospective**

Last update: **2023-12-17, 1402/09/26**

Update count: **0**

Registration date

2023-12-17, 1402/09/26

Registrant information

Name

Gholamhasan Esfahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 572 4252

Email address

esfahani.gh@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-09, 1402/10/19

Expected recruitment end date

2024-03-09, 1402/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of niacin addition to Escitalopram in patients with depression

Public title

The effect of niacin in the treatment of depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Score 11 to 18 in Hamilton depression test
Diagnosis of mild and moderate depression based on structured interview based on DSM-5 and Hamilton index
Age 18 to 60 years

Exclusion criteria:

Received electric shock in the last two months
Thyroid diseases
Psychotic disorder
pregnant women
severe depression
Allergy to niacin

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with eligibility criteria will be divided into two groups using a randomized block design. An online website (<https://www.sealedenvelope.com>) is used to generate a random list based on the desired sample size and block size of 4. After creating a list, each patient will be identified with a unique code throughout the study. 33 people are selected for the intervention group and 33 people for the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be evaluated by another specialist as part of the main research, and the design will be done in a double-blind manner. The patients' medications are adjusted by a nurse unrelated to the research and given to the patients so that the patients will not know the type of medication they are taking.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jundishapur Ahvaz University of Medical Sciences

Street address

Golestan BLVD

City

Ahvaz

Province

Khouzestan

Postal code

6441945781

Approval date

2023-11-27, 1402/09/06

Ethics committee reference number

IR.AJUMS.REC.1402.447

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

Depression score

Timepoint

Before the intervention, 2, 4, and 8 weeks after the intervention

Method of measurement

Clinical examination with Hamilton's index

Secondary outcomes

1

Description

Side effects of niacin

Timepoint

Before the intervention, 2, 4, and 8 weeks after the intervention

Method of measurement

Clinical examination

Intervention groups

1

Description

Intervention group: The intervention group (33 people) will receive niacin (Abidi Pharmaceuticals co.) supplement in addition to EScitalopram (Abidi Pharmaceuticals co.) as an anti-depressant drug. Niacin supplementation starts with half a gram and increases

half a gram every 0 weeks.

Category

Treatment - Drugs

2**Description**

Control group: The control group (33 people) will receive a placebo in addition to the Escitalopram (Abidi Pharmaceuticals co.) drug for eight weeks. The evaluation will be done by a psychiatrist. Escitalopram drug started with 6 mg daily and reached 18 mg in the second week.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Neurology and Psychiatry Clinic, Golestan Ahvaz Hospital

Full name of responsible person

Gholamhasan Esfahani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

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6135715794

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zakerkish-m@ajums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Gholamhasan Esfahani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Latest degree
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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

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