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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Contact

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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
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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