

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effect of Escitalopram versus placebo trial on changing the neuroticism

Protocol summary

Study aim

Evaluation of the effect of Escitalopram versus placebo on changing the neuroticism

Design

The subjects are residents of Golestan, Razi, and Imam hospitals in Ahvaz. Neuroticism will be assessed by conducting an initial interview and using the 60-item NEO-60 questionnaire at the beginning of the study, and if the neuroticism is confirmed in the individual and the entry and exit conditions are met, the study will be entered. Citalopram will be taken at a dose of 20 mg per day in patients and the other group will receive a placebo. Participants in the study will be blind to the intervention. The evaluation of neuroticism in the treatment and placebo group will be assessed at the beginning, the second and fourth weeks.

Settings and conduct

This clinical trial will be performed on 172 patients with control group, in parallel. Participants in this study will be blind to the type of intervention. The aim of this intervention is to evaluate the effect of Citalopram vs. placebo on altering the neuroticism traits. This study will be performed on residents in Ahvaz. Patient allocation will be non-random.

Participants/Inclusion and exclusion criteria

Included criteria: neuroticism traits based on NEO-60 questionnaire with a score higher than 24; age-range 24-45 years old. Excluded criteria: pregnancy; breastfeeding; psychiatric disorder based on GHQ questionnaire with a score above 23; previous history of intolerance to SSRI antidepressants; patients with a history of chronic diseases such as brain, cardiovascular, seizures and people with a history of drug abuse.

Intervention groups

This study is a randomized placebo-controlled clinical trial that will be performed on individuals in the age range of 24 to 45 years with neurotic traits above 24 for 4 weeks.

Main outcome variables

Flexibility; responsibility; psychotic; extraversion

General information

Reason for update

In the abstract part of the protocol, the method and place of the study needed to be amended. (Inpatients have been written incorrectly). The people under investigation are residents of Golestan, Razi and Imam hospitals in Ahvaz. They are not "hospitalized".

Acronym

IRCT registration information

IRCT registration number: **IRCT20211208053331N1**
Registration date: **2022-07-03, 1401/04/12**
Registration timing: **prospective**

Last update: **2022-09-15, 1401/06/24**

Update count: **1**

Registration date

2022-07-03, 1401/04/12

Registrant information

Name

Mina Kianmanesh rad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Escitalopram versus placebo trial on changing the neuroticism

Public title

Evaluation of the effect of Escitalopram versus placebo trial on changing the neuroticism

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Neuroticism traits based on NEO-60 questionnaire with a score higher than 24 Age-range 24-45 years old Obtaining informed consent from the individuals

Exclusion criteria:

Pregnancy or intention to conceive Lactation Presence of psychiatric disorder based on GHQ questionnaire with a score above 23 Previous history of SSRI antidepressant intolerance Patients with severe side effects of citalopram Patients with a history of chronic diseases such as brain and heart disease, vascular, seizures People with a history of drug abuse.

Age

From **24 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **172**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Subjects will be randomly divided into two groups of treatment and placebo. Citalopram S will be used in patients treated at a dose of 20 mg per day and the other group received a placebo. Participants will be blind to the treatment method and the drug used.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of ahvaz University of Medical Sciences

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Ahvaz Jondishapur University of Medical Sciences, Esfand ave., Golestan ave.

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Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2021-06-22, 1400/04/01

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.063

Health conditions studied**1****Description of health condition studied**

Neuroticism or neuroticism

ICD-10 code

F43.11

ICD-10 code description

Post-traumatic stress disorder, acute

Primary outcomes**1****Description**

Flexibility

Timepoint

At the beginning of the study, 2 and 4 weeks after intervention

Method of measurement

Personality Inventory-Revised questionnaire

2**Description**

Responsibility

Timepoint

At the beginning of the study, 2 and 4 weeks after intervention

Method of measurement

Personality Inventory-Revised questionnaire

3**Description**

Psychotic

Timepoint

At the beginning of the study, 2 and 4 weeks after intervention

Method of measurement

Personality Inventory-Revised questionnaire

4

Description

Extraversion

Timepoint

At the beginning of the study, 2 and 4 weeks after intervention

Method of measurement

Personality Inventory-Revised questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Subjects aged 24-45 years with neuroticism traits above 24 will be treated with Escitalopram at a dose of 20 mg/day for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo will be performed on subjects aged 24 to 45 years with neuroticism traits above 24 for 4 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Mina Kianmanesh Rad

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Recruitment center

Name of recruitment center

Razi hospital

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3

Recruitment center

Name of recruitment center

Emam Khomeyni hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

Shahin Norouzi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After the article is published, the results will be available to the public.

When the data will become available and for how long

After the article is published, the results will be available to the public.

To whom data/document is available

After the article is published, the results will be available to the public.

Under which criteria data/document could be used

I have not decided yet - the release schedule is not yet known

From where data/document is obtainable

I have not decided yet - the release schedule is not yet known

What processes are involved for a request to access

data/document

I have not decided yet - the release schedule is not yet known

Comments