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. Neurotomy 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 assess at the beginning, the second and forth 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
Street address
Ahvaz Jondishapur University of Medical Sciences, Esfand ave., Golestan ave.
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Khouzestan
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 nouroticism traits above 24 will be treated with Es citalopram 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 nouroticism 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
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Recruitment center
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Sponsors / Funding sources

1

Sponsor
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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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Person responsible for updating data

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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