Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

The effects of Duloxetine adjuantive treatment on Negative Symptoms of Schizophrenia

Protocol summary

Study aim
The effect of deloxitin on the negative symptoms of schizophrenia
Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment
Settings and conduct
In this double-blind randomized clinical trial study, 44 patients with schizophrenia with negative symptoms were recruited based on a structured clinical interview and DSM-IV basis at the Qods Hospital in Sanandaj or in outpatient clinics or centers. Patients in the intervention group were given 30 mg doloxetine in the first week and 60 mg daily in the second week to 7 weeks in addition to standard treatment. The positive and negative syndrome scale (PANSS) scale was evaluated at the beginning of the study, at week 4 and at the end of week 8. The drug and placebo are not recognizable, so a double-blind study is performed
Participants/Inclusion and exclusion criteria
Patients with schizophrenia؛Patients with prominent negative symptoms؛No severe depression in patients
Intervention groups
Patients in the intervention group were given 30 mg doloxetine in the first week and 60 mg daily in the second week until the 7th week. In the control group, the same dose was given to the control group.
Main outcome variables
Negative symptoms, positive symptoms, severity of psychiatric disorder, depression

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191218045795N2**
Registration date: **2020-04-04, 1399/01/16**
Registration timing: **retrospective**
Last update: **2020-04-04, 1399/01/16**
Update count: **0**
Registration date
2020-04-04, 1399/01/16

Registrant information
Name
Narges Shams alizadeh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-09-23, 1398/07/01
Expected recruitment end date
2020-02-04, 1398/11/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of Duloxetine adjuantive treatment on Negative Symptoms of Schizophrenia

Public title
The effect of Deluxitine on the negative symptoms of schizophrenia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Patients with schizophrenia Patients with prominent negative symptoms

Exclusion criteria:

major depression

Age

From **18 years** old to **59 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to the intervention and control groups using block randomization The patients will be randomly assigned to the intervention and control groups using block randomization Arrangement of the randomization process: 1) Determining the volume of each block (quadruple blocks) 2) Preparing the list of the blocks and assigning a number (between 1 and 6) to each of them 3)Choosing random numbers between 1 and 6 4) Defining the treatment assignment list

Blinding (investigator's opinion)

Double blinded

Blinding description

The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kordestan University of Medical Sciences

Street address

Niro entezami Blvd,Qods hospital

City

Sanandaj

Province

Kurdistan

Postal code

6617713141

Approval date

2018-09-25, 1397/07/03

Ethics committee reference number

IR.MUK.REC.1397.143

Health conditions studied

1

Description of health condition studied

Negative symptom

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Comparison of the positive and negative symptoms of schizophrenia

Timepoint

At baseline, 2, 4 and 8 weeks later

Method of measurement

Questionnaire for comparing positive and negative symptoms

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Deloxitin powder, manufactured by Dana Gostar Pharmaceuticals and weighed with 10 mg precision scales, is poured into the empty capsules. Patients receive 30 mg of deluxitine and antipsychotic capsules daily for one week, and from the second week, they are given two capsules of 60 mg daily, lasting for 7 weeks.

Category

Treatment - Drugs

2

Description

Control group: The control group received placebo, which is completely uniform, colorless and odorless with the drug. Patients were given placebo for one week and two capsules for the second week and continued for 7 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods hospital
Full name of responsible person
Narges Shams alizadeh
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Sponsors / Funding sources

1

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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
Sanandaj 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

2

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
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Yes
Title of funding source
Sanandaj 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
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Assistant professor
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
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