

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Study of the efficacy of naltrexone on positive and negative symptoms in schizophrenic patients

Protocol summary

Summary

Schizophrenia is a major disabling psychiatric disorder which is continually under investigation to reduce its destructive effects. Recently it has been suggested that naltrexone (an opioid antagonist) can be used for treatment of negative and positive symptoms of schizophrenia. This research has been designed to evaluate the efficacy of naltrexone in the negative and positive symptoms of the disorder. This is a double blind study. 30 patients with schizophrenia will be chosen in a random manner whom will be divided into two equal groups. In one group naltrexone will be added to the therapeutic regimen, while the other group will receive placebo instead of naltrexone. Inclusion criteria: all schizophrenic patients hospitalized in Farabi Hospital. Exclusion criteria: 1) Any patients who refuse to participate in the study. 2) any sensitivity to naltrexone. The PANSS questionnaire, Anderson test for positive and negative symptoms of schizophrenia, will be used in the beginning and at the end of the study. Naltrexone should be administered for 12 weeks and in a 100 mg/d dosage.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110093010N4**

Registration date: **2012-12-07, 1391/09/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-07, 1391/09/17

Registrant information

Name

Faeze Tatari

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 4618

Email address

ftatari@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the efficacy of naltrexone on positive and negative symptoms in schizophrenic patients

Public title

Study of the efficacy of naltrexone on positive and negative symptoms in schizophrenic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all schizophrenic patients hospitalized in Farabi Hospital. Exclusion criteria: 1) Any patients who refuse to participate in the study. 2) Any sensitivity to naltrexone.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Kermanshah University of Medical Sciences

Street address

Bilding 2., Kermanshah University of Medical Sciences, Shahi Beheshti blvd.

City

Kermanshah

Postal code**Approval date**

2012-09-22, 1391/07/01

Ethics committee reference number

پ/۷/۴۲۰/۳۲۶۳۸

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

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

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

Positive and negative symptoms

Timepoint

Before the intervention and after 12 weeks

Method of measurement

PaNSS (Anderson test) scores

Secondary outcomes

empty

Intervention groups**1****Description**

Placebo in cap form. 2 cap bid

Category

Placebo

2**Description**

Naltrexone cap. 2 cap bid.

Category

Treatment - Drugs

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

Kermanshah Farabi Hospital

Full name of responsible person

Dr Faezeh Tatari

Street address

Ashayer sq.

City

Kermanshah

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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

Street address

Bilding 2, Kermanshah University of Medical Sciences, Shahid Beheshti blvd.

City

Kermanshah

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Faezeh Tatari

Position

Psychiatrist/assistant professor

Other areas of specialty/work**Street address**

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Other areas of specialty/work**Street address**

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Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty