Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

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

Protocol summary

Summary

Schizophrenia is a major disabilitating 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)

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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 Scienses
Street address
Bilding 2., Kermanshah University of Medical Scienses, Shahi Beheshti blvd.
City
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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
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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

Person responsible for general inquiries

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Web page address

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