

# 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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ftatari@kums.ac.ir ; fztatari@yahoo.com

**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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**City**

Kermanshah

**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*