

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effectiveness of Pregabalin on Sleep Quality in Patients Receiving Methadone Maintenance Treatment: A Randomized double blind Clinical Trial

Protocol summary

Summary

Aim of this study will be assessment the effectiveness of pregabalin on sleep quality in patients under methadone maintenance treatment. This study will be a randomize double blind clinical trial. Inclusion criteria will include history of heroin dependency and patients under methadone maintenance treatment .Exclusion criteria will include age under 18 year and older than 75; starting methadone maintenance treatment less than 6 month; patients with major depressive disorder or psychosis based on psychiatrist visit and absence of any problem in sleep(PSQ sleep quality questionnaire score less than 5).population of this study will include patients under methadone maintenance treatment in methadone maintenance treatment clinics in Bojnurd, North eastern of IRAN. Sample size will be 140 participants. we will use computed generation random allocation for randomization .participants randomly will divide two groups and take either 75 mg day pregabalin before sleep or placebo for 8 week. Participants will accept 3 stage of assessment in 8 weeks (in the beginning, 4 week and 8 week after beginning) and then two groups will compare in term of change in sleep quality scores. We will use standard drug side effects checklist for assessment of possible side effects. This checklist will complete by therapists (physician) weekly for 8 week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021121045N1**

Registration date: **2015-11-12, 1394/08/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-11-12, 1394/08/21

Registrant information

Name

Seyed kaveh Hojjat

Name of organization / entity

North khorasan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

North khorasan University of Medical Sciences,Addiction and Behavioral Sciences Research Center

Expected recruitment start date

2016-01-10, 1394/10/20

Expected recruitment end date

2016-03-10, 1394/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Pregabalin on Sleep Quality in Patients Receiving Methadone Maintenance Treatment: A Randomized double blind Clinical Trial

Public title

Effectiveness of Pregabalin on Sleep Quality in Patients Receiving Methadone Maintenance Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: History of heroin dependency; patients under methadone maintenance treatment Exclusion criteria: Age under 18 year and older than 75; starting methadone maintenance treatment less than 6 month; PSQ sleep quality questionnaire score less than 5; patients with severe sleep disorder who need special treatment or major depressive disorder or psychosis based on psychiatrist visit; Participants with methadone maintenance dose lower than 60 mg/day or higher than 120 mg/day; Participant with using sedative- hypnotic drugs or heroin or methamphetamine during 8 week intervention

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

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

North khorasan University of Medical Sciences,Ethics committee

Street address

7 Plaque,Mohaghar Street,South Shariati Street,Bojnurd ,Deputy of Research,Ethics committee office

City

Bojnurd

Postal code

Approval date

2015-06-07, 1394/03/17

Ethics committee reference number

ir.nkums.rec.1394.3

Health conditions studied

1

Description of health condition studied

SUBSTANCE DEPENDENCY

ICD-10 code

F10

ICD-10 code description

A cluster of behavioural, cognitive, and physiological phenomena that develop after repeated substance use and that typically include a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences

Primary outcomes

1

Description

sleep quality

Timepoint

before intervention,week 4,week 8

Method of measurement

Pittsburgh sleep quality questionnaire

Secondary outcomes

1

Description

drug side effects

Timepoint

week 1-8,weekly

Method of measurement

standard side effects checklist

Intervention groups

1

Description

intervention group will receive one capsule (75 milligram) before sleep for 8 week.

Category

Treatment - Drugs

2

Description

control group will receive one capsule same shape and color with pregabalin before sleep for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

SABA methadone maintenance treatment center

Full name of responsible person

Dr seyed kaveh hojjat

Street address

17 Plaque, Mehregan Building ,Ordibehesht
Street, South Shariati Street, Bojnurd ,Deputy of
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2

Recruitment center

Name of recruitment center

bojnurd governmental methadone maintenance
treatment center

Full name of responsible person

dr hamid firozeh

Street address

9 PLAQUE, West Taleghani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

North khorasan University of Medical Sciences, Deputy
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Full name of responsible person

Dr Alireza Golshan

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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

North khorasan University of Medical Sciences, Deputy of
Research

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

Contact

Name of organization / entity

North khorasan university of

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Full name of responsible person

Dr seyed kaveh Hojjat

Position

Assistant professor of psychiatry, North khorasan
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Other areas of specialty/work

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**Person responsible for scientific
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Name of organization / entity

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Full name of responsible person

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Position

Assistant professor of psychiatry, Head of Addiction
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Other areas of specialty/work

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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