

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison effect of zolpidem and lorazepam on the severity of insomnia in methadone maintenance patients

Protocol summary

Summary

Objective: Comparative effect of zolpidem and lorazepam on the severity of insomnia in methadone maintenance patients The study is randomized and double -blind (Failure to inform patients and researchers of the drug inside the envelopes). Inclusion criteria: All addict patients treated with methadone and with severe insomnia Exclusion criteria: Medical and psychiatric illness that causes sleep disorders are serious. Use other hypnotic drugs before or during the study. Change the dose of methadone Study population: addicts treated with methadone with moderate to severe insomnia Sample size: 60 Patients were randomly assigned to two treatment groups with lorazepam 2 mg and zolpidem 10 mg for the 2 - week period The demographic data (ethnicity, gender, age, type of addiction, duration of addiction, narcotic type and duration of treatment) with Czech extracted list. To assess the sleep quality of the insomnia severity index (ISI) used. ISI has a 5-point scale. Scores are between 0 and 28.0-7 insomnia is not clinically significant. 8 to 14 below clinical threshold. 15-21 The average clinical insomnia. 22-28 Severe insomnia.If the patient with severe to moderate, moderate to mild improvement and effective treatment can be defined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081021309N2**
Registration date: **2015-10-08, 1394/07/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-08, 1394/07/16

Registrant information

Name

Mohammad Zaman Kamkar

Name of organization / entity

Golestan Research Center of Psychiatry

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Golestan University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of zolpidem and lorazepam on the severity of insomnia in methadone maintenance patients

Public title

the effect of zolpidem and lorazepam on the severity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All addict patients treated with methadone and with severe insomnia Exclusion criteria: Medical and psychiatric illness that causes sleep disorders are serious. Use other hypnotic drugs before or during the study. Change the dose of methadone

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Golestan University of Medical Sciences

Street address

Deputy of Research and Technology, Golestan
University of Medical Sciences

City

Gorgan

Postal code

4934174515

Approval date

2015-08-02, 1394/05/11

Ethics committee reference number

IR.GOUMS.REC.1394.62

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

severe insomnia

ICD-10 code

F40, F41,

ICD-10 code description

Neurotic, stress-related and somatoform disorders

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

Insomnia

Timepoint

at the beginning of study

Method of measurement

ISI Insomnia Questionnaire

Secondary outcomes

empty

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

Intervention Group: 30 Patients Name of consumer:

Zolpidem Dosage: 10 mg Time consumption: 2 weeks

Category

Treatment - Drugs

2**Description**

Control Group: 30 Patients Name of consumer:

Lorazepam Dosage: 2 mg Time consumption: 2 weeks

Category

Treatment - Drugs

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

Gorgan MMT(Methadone Maintenance Treatment)

Full name of responsible person

Dr Mohammad Zaman kamkar

Street address**City**

Gorgan

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

Deputy of Research and Technology, Golestan
University of Medical Sciences

Full name of responsible person

Dr Masoud khoshnia

Street address

Deputy of Research and Technology, Golestan
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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

Deputy of Research and Technology, Golestan 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

Contact

Name of organization / entity

Golestan Research Center of Psychiatry

Full name of responsible person

Dr Mohammad Zaman Kamkar

Position

Director of Research Center of Psychiatry

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