

# 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)

##### Phone

+98 17 3232 8051

##### Email address

dr.kamkar@goums.ac.ir

#### 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  
University of Medical Sciences

**City**

Gorgan

**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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**Position**

Assistant Professor of Psychiatry

**Other areas of specialty/work**

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Dr Mohammad Zaman Kamkar

**Position**

Assistant Professor 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*