

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Lorazepam and Zolpidem effect on insomnia in bone marrow transplantation patients

Protocol summary

Summary

Purpose of study: Comparison of Lorazepam and Zolpidem effect on insomnia. Study design: randomized, single blind, placebo not used, single recruitment center. Main inclusion criteria: Bone marrow transplantation patients that have insomnia base on SleepMed Insomnia Index questionnaire. Main exclusion criteria: Use of alcohol; Patients who have no remission in insomnia after taking 4 mg Lorazepam or 10 mg Zolpidem during 4 days; Addiction to opioids. Sample size: 35. Intervention: Medication initiates with 1 mg Lorazepam or 5 mg Zolpidem before nocturnal sleep. If the patient already takes another Benzodiazepine, it switches to Lorazepam with equivalent dose. Intervention time: 1 month. Outcomes: characteristics and severity of the insomnia complaint in nocturnal sleep using scores obtain from the SleepMed Insomnia Index questionnaire, degree of day time sleepiness using Epworth Sleepiness Scale questionnaire and anxiety and depression using the Hospital Anxiety and Depression Scale questionnaire. Simultaneously patients are considered about side effects of drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811103210N2**
Registration date: **2011-10-16, 1390/07/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-16, 1390/07/24

Registrant information

Name

Maria Tavakoli Ardakani

Name of organization / entity

Faculty of pharmacy, Shaid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2010-11-07, 1389/08/16

Expected recruitment end date

2011-11-07, 1390/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Lorazepam and Zolpidem effect on insomnia in bone marrow transplantation patients

Public title

Comparison of Lorazepam and Zolpidem effect on insomnia in bone marrow transplantation patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Bone marrow transplantation patients that have insomnia base on the SleepMed Insomnia Index questionnaire; Patients in range of 18-65 years old. Exclusion criteria: Sensitivity to Lorazepam or Zolpidem;

Narrow-angle glaucoma; Pregnancy & breast feeding; Hepatic encephalopathy; Rising of hepatic enzymes (AST, ALT, ALP, LDH) 3 times the upper limit of normal; Serum creatinine concentration more than 2.5 mg/dl; Use of alcohol; Patients who have no remission in insomnia after taking 4 mg Lorazepam or 10 mg Zolpidem during 4 days; Addiction to opioids

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethnics committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak street, Shaheed Chamran highway

City

Tehran

Postal code

Approval date

2010-11-07, 1389/08/16

Ethics committee reference number

91

Health conditions studied

1

Description of health condition studied

insomnia

ICD-10 code

G47.0

ICD-10 code description

Disorders of initiating and maintaining sleep

Primary outcomes

1

Description

sleepiness

Timepoint

Before intervention and 1, 2, 3 and 4 week after beginning of intervention

Method of measurement

Epworth sleepiness scale questionnaire

2

Description

Anxiety and Depression

Timepoint

Before intervention and 4 week after beginning of intervention

Method of measurement

Hospital Anxiety and Depression Scale questionnaire

3

Description

Insomnia

Timepoint

Before intervention and 1, 2, 3 and 4 weeks after beginning of intervention

Method of measurement

SleepMed Insomnia Index questionnaire

Secondary outcomes

1

Description

Central Nervous System side effects

Timepoint

1, 2, 3 and 4 week after beginning of intervention

Method of measurement

Clinical observation

2

Description

GastroIntestinal System side effects

Timepoint

1, 2, 3 and 4 week after beginning of intervention

Method of measurement

Clinical observation

Intervention groups

1

Description

Zolpidem, 5 mg oral tablet, once daily, before nocturnal sleep, during 1 month. it can increase up to 10 mg, for 4 days.

Category

Treatment - Drugs

2

Description

Lorazepam, 1 mg oral tablet, once daily, before nocturnal sleep, during 1 month. it can increase up to 4 mg for 4 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr Maria Tavakoli Ardekani

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Velenjak street, Shaheed Chamran highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Faculty of pharmacy,
Shaheed Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Valiasr Ave, Niayesh highway, Tehran, Iran

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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

Vice chancellor for research, Faculty of pharmacy,
Shaheed Beheshti 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

Faculty of pharmacy, Shahid Beheshti University of

Medical Sciences

Full name of responsible person

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Pharmacy student

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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