Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Zolpidem on sleep quality of Tehran firefighters

Protocol summary

Summary

Study objectives : To determine effect of Zolpidem on sleep quality of Tehran firefighters. The study design : Double Blind Randomized Controlled Crossover Trial The study population : Firefighters of Tehran Fire and Safety Services Organization Inclusion criteria : Firefighter of Tehran Fire and Safety Services Organization with poor sleep quality (PSQI>5) Exclusion criteria: Acute or chronic disease; Medication usage;Major stressor events during last 6 month Sample size : 20 Interventions : Zolpidem (Tablet 10mg) bed time for 14 days as intervention & placebo (Wheat flour) bed time for 14 days as control. Primary outcome : Overall sleep quality

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106076724N1**
Registration date: **2011-06-13, 1390/03/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-06-13, 1390/03/23

Registrant information

Name

Amir Hossein Naseri Esfahani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6640 5588

Email address

naseri_a@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of rsearch for Tehran University Of Medical sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Zolpidem on sleep quality of Tehran firefighters

Public title

Effect of Zolpidem on sleep quality of Tehran firefighters

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: firefighters of Tehran; global score of Pittsburgh Sleep Quality Index > 5 EXclusion criteria: Any acute or chronic disease; Medication usage; Major stressor events during last 6 month.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tehran University Of Medical Sciences

Street address

On The Corner of Keshavarz Blvd. and Qods Street, Keshavarz Blvd., Vali-e-asr Square

City

Tehran

Postal code

1417653761

Approval date

2011-06-06, 1390/03/16

Ethics committee reference number

130/1253/D

Health conditions studied

1

Description of health condition studied

sleep quality disorders

ICD-10 code

G47

ICD-10 code description

sleep disorders

Primary outcomes

1

Description

sleep quality

Timepoint

before intervention, after Zolpidem intervention & after placebo intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description

Problems has it been for each person to keep up enthusiasm to get things done

Timepoint

before intervention, after Zolpidem intervention & after placebo intervention

Method of measurement

face to face interview & sleep data recorded by each person

2

Description

Time of going to bed

Timepoint

before intervention, after Zolpidem intervention & after placebo intervention

Method of measurement

face to face interview & sleep data recorded by each person

3

Description

Time between going to bed and falling asleep

Timepoint

before intervention, after Zolpidem intervention & after placebo intervention face

Method of measurement

face to face interview & sleep data recorded by each person

4

Description

Time of waking up

Timepoint

before intervention, after Zolpidem intervention & after placebo intervention

Method of measurement

face to face interview & sleep data recorded by each person

5

Description

Hours of actual sleep (May be different than the number of hours each person spend in bed)

Timepoint

before intervention, after Zolpidem intervention & after placebo intervention

Method of measurement

face to face interview & sleep data recorded by each person

6

Description

Number of more than 30 minutes trying to fall asleep

Timepoint

before intervention, after Zolpidem intervention & after placebo intervention

Method of measurement

face to face interview & sleep data recorded by each person

7

Description
Number of waking up early morning or midnight
Timepoint
before intervention, after Zolpidem intervention & after placebo intervention
Method of measurement
face to face interview & sleep data recorded by each person

8

Description
Number of daytime sleepiness
Timepoint
before intervention, after Zolpidem intervention & after placebo intervention
Method of measurement
face to face interview & sleep data recorded by each person

9

Description
Other sleep problems
Timepoint
before intervention, after Zolpidem intervention & after placebo intervention
Method of measurement
face to face interview & sleep data recorded by each person

10

Description
Medication usage for sleep
Timepoint
before intervention, after Zolpidem intervention & after placebo intervention
Method of measurement
face to face interview & sleep data recorded by each person

11

Description
Self assessment about overall quality of his/her sleep
Timepoint
before intervention, after Zolpidem intervention & after placebo intervention
Method of measurement
face to face interview & sleep data recorded by each person

12

Description
Morning sleepiness
Timepoint
before intervention, after Zolpidem intervention & after placebo intervention (all in 8 am)
Method of measurement
ESS Questionnaire

Intervention groups

1

Description
Intervention : Tablet Zolpidem (HEXAL®) 10 mg bedtime for 14 days
Category
Treatment - Drugs

2

Description
Control : Wheat flour in same appearance of Zolpidem 2 gr bedtime for 14 days (Placebo)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fire stations in Tehran
Full name of responsible person
Amir Hossein Naseri Esfahani , MD , Resident of Occupational Medicine
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Baharloo Hospital, Occupational Medicine Center
Full name of responsible person
Naseri Esfahani AH, MD, Resident of occupational Medicine
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Siences
Full name of responsible person
Akbar Fotouhi, vice chancellor for research
Street address
On The Corner of Keshavarz Blvd. & Qods Street, Keshavarz Blvd., Vali-e-asr Square, Sixth Floor
City
Tehran
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, Tehran University of Medical Siences
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
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Person responsible for updating data

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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