

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 research 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 Sciences

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 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

MD, MPH, Associate Professor of Occupational Medicine

Other areas of specialty/work**Street address**

Poorsina St., School of Medicine, Occupational Medicine Department

City

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mehrdradr@tums.ac.ir

Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Amir Hossein Naseri Esfahani

Position

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Center for Research on Occupational Diseases, Tehran University of Medical Sciences

Full name of responsible person

Ramin Mehrdad

Position**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Amir Hossein Naseri Esfahani

Position

MD, Resident of occupational medicine

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occupationalmedicine@yahoo.com

Web page address**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