

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The study of efficacy of melatonin, and zolpidem on the sleep quality, and severity of pain in the patients with chronic non-specific low back pain

Protocol summary

Study aim

Determining efficacy of melatonin, and zolpidem on the sleep quality, and severity of pain in the patients with chronic non-specific low back pain

Design

In this research, 46 eligible patients with low back pain referring to Mahdiah Clinic in Kermanshah were chosen purposefully and were referred to Sleep Research Center and their pain was assessed and their sleep status were mentally and objectively assessed and they were randomly allocated in one of three groups of receiving: 1- melatonin, 2- zolpidem, and 3- placebo. After one month of physiotherapy treatment their pain and sleep quality were reassessed.

Settings and conduct

Physiotherapy treatment was done in Mahdiah Clinic in Kermanshah and pain and sleep status was assessed in Sleep Research Center of Kermanshah medical university.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having nonspecific low back pain, Age of 30-65 y, having insomnia. Exclusion Criteria: Having other sleep problems, having other musculoskeletal disorders.

Intervention groups

1- Receiving Melatonin 2- Receiving Zolpidem 3- Receiving Placebo

Main outcome variables

Sleep quality based on Pittsburgh questionnaire. Sleep quality based on Actigraphy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111109008035N4**

Registration date: **2017-12-29, 1396/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-29, 1396/10/08**

Update count: **0**

Registration date

2017-12-29, 1396/10/08

Registrant information

Name

MohammadBagher Shamsi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3838 4185

Email address

mshamsi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of efficacy of melatonin, and zolpidem on the sleep quality, and severity of pain in the patients with chronic non-specific low back pain

Public title

The study of efficacy of melatonin, and zolpidem on the sleep quality, and severity of pain in the patients with

chronic non-specific low back pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with non-specific low back pain who complain of insomnia and poor quality of sleep for more than 1 month.
Exclusion criteria:
Herniated lumbar discopathy; malignancy; sleep apnea; psychosis; drug abuse; past history of other sleep disorders and medical problems affecting sleep quality such as diabetes mellitus & chronic renal failure.

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Table of random numbers will be used.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants are blind. The psychologist who will do assessment of pain intensity and also sleep quality mentally (by questionnaire) and objective (by actigraph) and the physiotherapist who will physically treat the participants are blind too.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences,

Street address

Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2017-09-27, 1396/07/05

Ethics committee reference number

IR.KUMS.ERC.1396.348

Health conditions studied

1

Description of health condition studied

Low Back Pain

ICD-10 code

M54.9

ICD-10 code description

Dorsalgia, unspecified

Primary outcomes

1

Description

Sleep quality

Timepoint

At the start and end of the study

Method of measurement

Pittsburgh questionnaire and Actigraphy

Secondary outcomes

1

Description

Visual Analogue Scale

Timepoint

At the start and end of the study

Method of measurement

Visual Analogue Scale

2

Description

Disability

Timepoint

At the start and end of the study

Method of measurement

With Oswestry disability index

Intervention groups

1

Description

Melatonin or N-acetyl-5-methoxy tryptamine 3 milligrams per night for one month (during 20 physiotherapy sessions on alternate days)

Category

Treatment - Drugs

2

Description

Zolpidem or Ambien 5 milligrams per day for one month
(during 20 physiotherapy sessions on alternate days)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Outpatient Clinic of Kermanshah University of Medical
Sciences

Full name of responsible person

Mohammad Bagher Shamsi

Street address

Javanshir Street

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3827 9697

Email

mbshamsi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

Street address

Shahid beheshti Boulevard,

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3827 9697

Email

mbshamsi@yahoo.com

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

MohammadBagher Shamsi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Kermanshah University of Medical Sciences, Shahid
Behshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3724 1929

Fax

Email

mbshamsi@yahoo.com

Web page address

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Kermanshah University of Medical Sciences,

Full name of responsible person

MohammadBagher Shamsi

Position

PhD

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Kermanshah University of Medical Sciences, Shahid
Behshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3724 1929

Fax

Email

mbshamsi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

MohammadBagher Shamsi

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

Physiotherapy

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+98 83 1724 1929

Fax

Email

mbshamsi@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All collected deidentified data will be shared with others.

When the data will become available and for how long

Starting 6 months after relative manuscript publication.

To whom data/document is available

Researchers working in academic institutions or people working in businesses can also apply to receive it.

Under which criteria data/document could be used

No access criteria for data/documents.

From where data/document is obtainable

Correspond with Dr MohammadBagher Shamsi.

What processes are involved for a request to access data/document

Correspond with and email to Dr MohammadBagher Shamsi.

Comments