

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of Transcutaneous Electrical Acupoint Stimulation on sleep quality in patient with chronic insomnia

Protocol summary

Summary

Objective: the effect of electrical stimulation of acupuncture points on the quality of sleep in patients with chronic insomnia. Design: randomized single-blind control groups with a sample size of 40 people in two groups of 20 cases and controls. Inclusion criteria: no pacemakers in heart; healthy upper and lower limbs. Exclusion criteria: severe psychological trauma during the study and using sleep drugs. Sample size: 40. Intervention: electrical stimulation of acupuncture points intervening time: 8 sessions a month each session 5 minutes. Primary outcomes: improved sleep quality in patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060634353N1**

Registration date: **2017-06-19, 1396/03/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-06-19, 1396/03/29

Registrant information

Name

Soroush Maazinezhad

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Transcutaneous Electrical Acupoint Stimulation on sleep quality in patient with chronic insomnia

Public title

The effect of Transcutaneous Electrical Acupoint Stimulation on sleep quality

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: no pacemakers in heart; healthy upper and lower limbs. Exclusion criteria: severe psychological trauma during the study and using sleep drugs.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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
Kermanshah University of Medical Sciences
Street address
Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.
City
Kermanshah
Postal code
Approval date
2017-05-17, 1396/02/27
Ethics committee reference number
IR.KUMS.REC.1396.81

Health conditions studied

1

Description of health condition studied
Chronic insomnia
ICD-10 code
G47.0
ICD-10 code description
Disorders of initiating and maintaining sleep [insomnias]

Primary outcomes

1

Description
sleep quality
Timepoint
Before and one month after intervention
Method of measurement
Using the Pittsburgh Sleep Quality Index and Actigraphy

Secondary outcomes

1

Description
The little red-site irritation

Timepoint
After intervention
Method of measurement
Find and physical examination

Intervention groups

1

Description
Control group: only contacts with the same points without electrical stimulation probe
Category
Treatment - Other

2

Description
Intervention group: electrical stimulation of acupuncture points on the skin three points H7 and SP6 and L14.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sleep Research Center, Kermanshah University of Medical Sciences
Full name of responsible person
Soroush Maazinezhad
Street address
Farabi hospital, Dolat Abad blvd.
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences / Vice Chancellor for Research and Technology
Full name of responsible person
Koorosh Hamzehi
Street address
Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.
City
Kermanshah
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 / Vice Chancellor for Research and Technology
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

Kermanshah University of Medical Sciences

Full name of responsible person

Soroush Maazinezhad

Position

Psychiatric Nursing Graduate Student

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