Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Randomized-controlled trial on Electromagnetictherapy for treatment of insomnia

Protocol summary

Summary

This study, that was a random single blind clinical trial, was done on 60 people who have referred to the office of the neurologist and according to the DSM-IV criteria, their diagnosis has been determined. The samples were determined according to similar studies and random number distributions. They were placed in 2 groups of 30 people with electromagnetic and control (treatment with Alperazolam) and they were treated for 3 weeks. Using the questionnaire of studying the quality of sleep Pitssburgh(PSQI) also the questionnaire of the study of the severity of the insomnia (ISI) of the patients in 3 periods before the study and immediately after the treatment and 1 month after treatment were evaluated and the results were analyzed statistically.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112128382N1**
Registration date: **2011-12-28, 1390/10/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-12-28, 1390/10/07

Registrant information

Name

Farid Gossili

Name of organization / entity

Ardebil university of medical sciences

Country

Iran (Islamic Republic of)

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+98 45 1771 5737

Email address

farid_gossili@yahoo.com

Recruitment status

Recruitment complete

Funding source

1.Ardebil University Of Medical Sciences 2.Mehr Physiotherapy Clinic Of Ardebil

Expected recruitment start date

2007-09-23, 1386/07/01

Expected recruitment end date

2008-09-22, 1387/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized-controlled trial on Electromagnetictherapy for treatment of insomnia

Public title

Electromagnetictherapy for treatment of insomnia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1.According to the DSM-IV criteria, their diagnosis has been determined 2. Their insomnia has lasted for 3 weeks 3.The patient didn't have other problems such as PUD,COPD,IHD,CHF,CVA,Asthmaand etc Exclusion criteria: 1.Happening side effects 2.Not appropriate participation of patients

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ardebil university of medical sciences
Street address
Daneshgah boulevard
City
Ardebil
Postal code
Approval date
2009-07-09, 1388/04/18
Ethics committee reference number
8801/5

Health conditions studied

1

Description of health condition studied
primary insomnia
ICD-10 code
F51.0
ICD-10 code description
A condition of unsatisfactory quantity and/or quality of sleep, which persists for a considerable period of time, including difficulty falling asleep, difficulty staying asleep, or early final wakening. Insomnia is a common symptom of many mental and phys

Primary outcomes

1

Description
Insomnia
Timepoint
The patients in 3 periods before the study and immediately after the treatment and 1 month after treatment were evaluated
Method of measurement
The questionnaire Pitssburgh Sleep Quality Index(PSQI) also the questionnaire Insomnia Severity Index (ISI)

Secondary outcomes

empty

Intervention groups

1

Description
In the treatment group, patients treated with electromagnetic therapy and 3 weeks for 6 sessions, each session 20 minutes with a frequency of 10 Hz and 35%, with trans-cranial electromagnetic therapy were PMT Quattro.
Category
Treatment - Devices

2

Description
Alprazolam 1 mg tablet daily in the control group patients were treated for 3 weeks,Controls to prevent patients from the placebo effect of the electromagnetic device therapy for 6 sessions in 3 weeks, but no waves were electromagnetic therapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatrists in private practice in Ardebil
Full name of responsible person
Dr Parviz Molavi
Street address
City
ardebil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardebil University Of Medical Sciences
Full name of responsible person
Rasool Lotfollahzadeh
Street address
Daneshgah Boulevard
City
Ardebil
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardebil 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

Ardebil University Of Medical Sciences

Full name of responsible person

Farid Gossili

Position

General Practitioner

Other areas of specialty/work

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Person responsible for updating data

Contact

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