

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of Acupuncture and sleep hygiene on insomnia during pregnancy

Protocol summary

Study aim

Acupuncture seems to offer an alternative treatment for insomnia. An increase in the serum concentration of melatonin is induced by acupuncture. Since this is usually lowered in pregnant women with sleeping difficulties, this may be one mechanism for the effect. Therefore the aim of this study was to survey the effects and safety of acupuncture on the treatment of insomnia during pregnancy.

Design

66 patients were randomly divided into 3 groups of 22, including: control group, sleep group and traditional medicine group.

Settings and conduct

The present study was designed as a prospective clinical trial which was performed on 66 outpatients pregnant women who complain from insomnia who referred to Hafez and Hazrat zeinab hospitals shiraz University of medical sciences. Individuals in one group (n=22) received acupuncture therapy 20 min daily for 2 weeks (group acupuncture). On the other group (n=22), individuals received education of sleep hygiene (sleep hygiene group). Third group (n=22) was control group. The effect of interventions on to the quality and patterns of sleep were assessed at the end of 2 weeks of treatment using Pittsburgh sleep quality index.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 15-39, pregnant women 12-37, non-history of insomnia and mental disorders
Exclusion criteria: History of depression or insomnia, high risk pregnancy

Intervention groups

Individuals in one group (n=22) received acupuncture therapy 20 min daily for 2 weeks (group acupuncture). On the other group (n=22), individuals received education of sleep hygiene (sleep hygiene group). Third group (n=22) was control group. The effect of interventions on to the quality and patterns of sleep were assessed at the end of 2 weeks of treatment using Pittsburgh sleep quality index.

Main outcome variables

Comparison of the score of the Pittsburgh Sleep Disorders Questionnaire after the intervention was considered as the primary outcome of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140525017827N4**

Registration date: **2017-12-25, 1396/10/04**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-25, 1396/10/04**

Update count: **0**

Registration date

2017-12-25, 1396/10/04

Registrant information

Name

Nasrin Asadi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 2365

Email address

asadin@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-01, 1396/09/10

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Acupuncture and sleep hygiene on insomnia during pregnancy

Public title
Effect of Acupuncture and sleep hygiene on insomnia during pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with aged between 15-39years .Gestational aged between 12 and 37weeks Not having a history of insomnia and mental disorders
Exclusion criteria:

Age
From **15 years** old to **39 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**
Actual sample size reached: **66**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Headquarters Of Shiraz University of Medical Sciences - Zand St - Shiraz
City
Shiraz
Province
Fars
Postal code

14336 - 71348

Approval date
2015-04-29, 1394/02/09

Ethics committee reference number
IR.SUMS.MED.REC.1394.01

Health conditions studied

1

Description of health condition studied
Nonorganic insomnia
ICD-10 code
F51.0
ICD-10 code description
maternal disorders predominantly related to pregnancy

Primary outcomes

1

Description
Comparison of the score of Pittsburgh Sleep Disorders Questionnaire after the intervention
Timepoint
Before and after the intervention
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 22 patients received acupuncture therapy 20 min daily for 2 weeks
Category
Treatment - Other

2

Description
Control group: 22 patients received education of sleep hygiene for 2 weeks
Category
Behavior

3

Description
Control group: 22 patients are monitored for 2 weeks.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Clinic of Shiraz University of Medical Sciences

Full name of responsible person

Zahra Khosravi

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Shahid Chamran blvd, Hafez Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyed Baser Hashemi

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Building of Shiraz University of Medical Sciences,
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hashemib@sums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Khosravi

Position

Resident of obstetrics and gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Department of obstetrics and gynecology, Shahid
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Person responsible for scientific inquiries

Contact

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Nasrin Asadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Completion of Ethic form

When the data will become available and for how long

After completing the project

To whom data/document is available

Patient or guardian

Under which criteria data/document could be used

Notice the result of the treatment

From where data/document is obtainable

Department of obstetrics and gynecology, Shahid Faghihi Hospital

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

Request a letter to the research vice president

Comments