Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 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)

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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

Street address
Shahid Chamran blvd, Hafez Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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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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