

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of acupressure versus no acupressure on sleep quality in pregnant women in the third trimester of pregnancy with sleep disorder: a single-blind crossover randomized clinical trial

Protocol summary

Study aim

To assess the effect of acupressure versus no acupressure on sleep quality in pregnant women in the third trimester of pregnancy with sleep disorder

Design

This is a single-blind crossover randomized clinical trial, phase II, in which 56 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible 56 pregnant women in the third trimester of pregnancy who will refer to Health Centers of Hamadan City during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 35 years; Pregnant women in the third trimester of pregnancy; Unsuitable sleep quality based on Pittsburg criteria (score of 5 or more); Singleton pregnancy Exclusion criteria: High-risk pregnancy; A history of infertility; Ulcer and skin problems; Psychological disorder; Cancer; Advance cardiovascular disease; Insulin-dependent diabetes mellitus; A history of acupuncture or acupressure

Intervention groups

Intervention group: Applying pressure on Shen Man's true points on both hands for 2 minutes (5 minutes in every point and 2 minutes rest) three time a week for 3 weeks Control group: Applying pressure on Shen Man's false points on both hands for 2 minutes (5 minutes in every point and 2 minutes rest) three time a week for 3 weeks

Main outcome variables

Primary outcome: Assessing the quality of sleep before intervention and 3 weeks after intervention using Pittsburg questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N241**

Registration date: **2018-10-12, 1397/07/20**

Registration timing: **prospective**

Last update: **2018-10-12, 1397/07/20**

Update count: **0**

Registration date

2018-10-12, 1397/07/20

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-11-06, 1398/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of acupressure versus no acupressure on sleep quality in pregnant women in the third trimester of pregnancy with sleep disorder: a single-blind crossover randomized clinical trial

Public title

Effect of acupressure versus no acupressure on sleep quality in pregnant women in the third trimester of pregnancy with sleep disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 35 years; Pregnant women in the third trimester of pregnancy; Unsuitable sleep quality based on Pittsburg criteria (score of 5 or more); Singleton pregnancy

Exclusion criteria:

High-risk pregnancy; A history of infertility; Ulcer and skin problems; Psychological disorder; Cancer; Advance cardiovascular disease; Insulin dependent diabetes mellitus; A history of acupuncture or acupressure

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the tossing coin

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be unaware of the true and false pressure point. Therefore, the trial will be run as a single-blind

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

1990-06-09, 1369/03/19

Ethics committee reference number

IR.UMSHA.REC.1397.164

Health conditions studied

1

Description of health condition studied

Sleep disorder

ICD-10 code

F51

ICD-10 code description

Sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description

Assessing the quality of sleep

Timepoint

Before intervention and 3 weeks after intervention

Method of measurement

Using Pittsburg questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Applying pressure on Shen Man's true points on both hands for 2 minutes (5 minutes in every point and 2 minutes rest) three time a week for 3 weeks

Category

Treatment - Other

2

Description

Intervention group: Applying pressure on Shen Man's true points on both hands for 2 minutes (5 minutes in every point and 2 minutes rest) three time a week for 3 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers of Hamadan City

Full name of responsible person

Dr. Seyyedeh Zahra Masoomi

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

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6517838695

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Email

Zahramid2001@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Seyyedeh Zahra Masoomi

Position

Fertility Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Seyyedeh Zahra Masoomi

Position

Fertility Health Specialist

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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

Undecided - It is not yet known if there will be 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