

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

Hamadan

**Province**

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**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**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**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

**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

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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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**Email**

poorolajal@umsha.ac.ir

**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