

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effect of Warm and Cold Foot bath on Severity of Restless Legs Syndrome and sleep quality

#### Protocol summary

##### Summary

The aim of this study was to Comparative effect of Warm and Cold Foot bath on Severity of Restless Legs Syndrome and sleep quality in pregnant women. Inclusions criteria included: Pregnancy age was 34-20 weeks; mental health; ability to read and write. Exclusion criteria included: cold or heat sensitivity; use sleep medication; Pregnancy illness; ulcer and lower limb pain. This is a randomized clinical trial study. 80 pregnant women with restless leg syndrome were randomly divided into two intervention groups (1 and 2). Each night, for group 1 was asked to wash their legs for 2 weeks with Cold water at 20 to 25 degrees for 10 minutes. Each night, for the group 2 was asked to wash their legs for 2 weeks with warm water at 40 to 45 degrees for 10 minutes. At baseline and at the end of the study, the severities of restless leg syndrome and sleep quality were measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017072414229N6**  
Registration date: **2017-08-13, 1396/05/22**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-08-13, 1396/05/22

##### Registrant information

##### Name

Hadi Jafari manesh

##### Name of organization / entity

Arak University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3503

##### Email address

jafarimanesh@arakmu.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2018-09-23, 1397/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Warm and Cold Foot bath on Severity of Restless Legs Syndrome and sleep quality

##### Public title

Comparative effect of Warm and Cold Footbath on Severity of Restless Legs Syndrome and sleep quality in pregnant women

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusions criteria included: Pregnancy age was 34-20 weeks; mental health; ability to read and write. Exclusion criteria included: cold or heat sensitivity; use sleep medication; Pregnancy illness; ulcer and lower limb pain.

##### Age

From **18 years** old to **60 years** old

##### Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 80

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

##### Street address

Basij Sq. Arak

##### City

Arak

##### Postal code

3819693345

#### Approval date

2017-08-23, 1396/06/01

#### Ethics committee reference number

IR.ARAKMU.REC.1396

## Health conditions studied

### 1

#### Description of health condition studied

Normal pregnancy

#### ICD-10 code

z34.8

#### ICD-10 code description

Supervision of other normal pregnancy

## Primary outcomes

### 1

#### Description

Restless Leg Syndrome

#### Timepoint

Before and after 2 weeks

#### Method of measurement

Restless Leg Syndrome Questionnaires

## Secondary outcomes

### 1

#### Description

Quality of Sleep

#### Timepoint

Before and after 2 weeks

#### Method of measurement

Petersburg Sleep Quality Questionnaire

## Intervention groups

### 1

#### Description

Foot bath for 2 weeks with Cold water at 20 to 25 degrees for 10 minutes

#### Category

Other

### 2

#### Description

Foot bath for 2 weeks with warm water at 40 to 45 degrees for 10 minutes

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani Hospital

##### Full name of responsible person

Hadi Jafari Manesh

##### Street address

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Rafiei

##### Street address

Deputy of Research and Technology, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

##### City

Arak

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Hadi Jafari Manesh

**Position**

Master of Nursing

**Other areas of specialty/work**

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**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*