

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

Street address

Basij Sq. Arak

City

Arak

Postal code

Phone

+98 86 3417 3503

Fax

Email

hadijafarimanesh@arakmu.ac.ir

Web page address

Person responsible for scientific 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

Street address

Basij Sq. Arak

City

Arak

Postal code

Phone

+98 86 3417 3503

Fax

Email

nurse_science@yahoo.com

Web page address

Person responsible for updating data

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

Street address

Basij Sq. Arak

City

Arak

Postal code

Phone

+98 86 3417 3503

Fax

Email

Web page address

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