Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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