Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of local heat on restless legs syndrome and excessive fatigue in nurses working in the intensive care unit

Protocol summary

Study aim
The effect of local heat on restless legs syndrome and extreme fatigue in nurses working in intensive care units

Design
After determining the patients with restless legs syndrome, they will be assigned to groups A (test group) and B (control group) using quadruple blocks. The researcher will be treated with a warm water bag for 12 weeks in 12 sessions. After the intervention, the post-test (completing Restless legs Syndrome and Fatigue Questionnaire) will be performed.

Settings and conduct
The study population will be comprised of nurses working in intensive care units. The nurses participating in the study will be randomly selected and divided into two groups of experimental and control. The intervention of the experimental group will be done for 4 weeks in 12 sessions. Due to the nature of the study it is not possible to be blinded.

Participants/Inclusion and exclusion criteria
Entry requirements : Having at least one year of work experience Undergraduate degree Restless leg syndrome Physicians working in intensive care units Exit conditions: Taking medication and supplements People taking painkillers and opiates within 72 hours before the study Consumers of psychotropic drugs Neuromuscular disorders and arthritis Pregnant women Wounds and redness of the limbs Heat sensitivity Vascular diseases and diabetes

Intervention groups
The intervention will last for 4 weeks in 12 sessions. The hot water bag is placed intermittently under both legs of the nurses.

Main outcome variables
The variables of this study include restless legs syndrome and fatigue. For this purpose, demographic questionnaire, international standard questionnaire for standing legs syndrome and smeth fatigue questionnaire (MFI) will be provided to nurses from intensive care unit.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190723044316N1**
Registration date: **2019-10-10, 1398/07/18**
Registration timing: **prospective**

Last update: **2019-10-10, 1398/07/18**
Update count: **0**

Registration date
2019-10-10, 1398/07/18

Registrant information

Name
maryam ameri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3223 3277

Email address
maryam19_2006@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-12, 1398/07/20

Expected recruitment end date
2019-11-11, 1398/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of local heat on restless legs syndrome and excessive fatigue in nurses working in the intensive care unit

Public title
effect of local heat on restless legs syndrome and excessive fatigue in nurses
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a year of experience Undergraduate degree Restless leg syndrome Physicians working in intensive care units
Exclusion criteria:
Taking Medication and Supplements People taking painkillers and opiates within 72 hours before the study Consumers of psychotropic drugs Neuromuscular disorders and arthritis Pregnant women Wounds and redness of the limbs Heat sensitivity Vascular diseases and diabetes
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
After determining the patients with restless legs syndrome, they will be assigned to groups A (test group) and B (control group) using quadruple blocks.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences
Street address
Shahroud - Haft Tir Square - Shahroud University of Medical Sciences
City
Shahroud
Province
Semnan
Postal code
۳۶۱۴۷-۷۳۹۴۷
Approval date
2019-09-30, 1398/07/08
Ethics committee reference number
IR.SHMU.REC.1398.079

Health conditions studied

1

Description of health condition studied
Restless leg syndrome
ICD-10 code
G25.81
ICD-10 code description
Restless legs syndrome

2

Description of health condition studied
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
One of the variables in this study is restless legs syndrome. To this end, the International Standard Questionnaire for Restless Legs Syndrome will be provided to nurses by intensive care unit.
Timepoint
The intervention of the experimental group will be done for 4 weeks in 12 sessions
Method of measurement
The intervention of the experimental group will be done for 4 weeks in 12 sessions after the end of the intervention the post-test will be re-tested and again the questionnaires will be completed by the test and control group and the results will be compared with the previous results.

2

Description
One of the variables of this study is excessive fatigue and for this purpose Smyths Fatigue Inventory (MFI) will be provided to the nurses of intensive care units.
Timepoint
The intervention of the experimental group will be done for 4 weeks in 12 sessions
Method of measurement
The intervention of the experimental group will be done for 4 weeks in 12 sessions after the end of the intervention the post-test will be re-tested and again the questionnaires will be completed by the test and control group and the results will be compared with the previous

results.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention of the experimental group will be conducted for 4 weeks in 12 sessions. After the end of the intervention the post-test will be taken and the questionnaires will be completed again by both groups and the results will be compared with the previous results. The hot water bag will be 40-43 ° C which is 1.3 to 2.3 It should be filled with warm water bags (for each nurse separate bag depending on the size of the body to the extent that it covers the surface of each foot) under the legs of the alternate nurse (because this syndrome occurs at night, Whether or not to do the shift by the person studied). The duration of bag usage will be 20 minutes based on the book of Nursing Principles and Techniques.

Category

Treatment - Devices

2

Description

Control group: Training is given only to the experimental group and no intervention is performed on the control group. After the intervention, the post-test group will receive post-test and again the questionnaires will be completed by both groups and the results will be compared with the previous results.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital - Spring Hospital - Khatam Al Anbia Hospital - Red Crescent Dialysis Center

Full name of responsible person

Maryam Ameri

Street address

Shahroud - Haft Tir Square - Shahroud University of Medical Sciences

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Phone

+98 23 3239 5054

Email

maryam19_2006@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hasan Emamian

Street address

Shahroud - Haft Tir Square – Shahroud University of Medical Sciences

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Phone

+98 23 3239 5054

Email

emamian@shmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Maryam Ameri

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahroud - Haft Tir Square - Shahroud University of Medical Sciences

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Phone

+98 23 3239 5054

Fax

Email

maryam19_2006@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Reza Khatibi

Position

science Committee

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahroud University of Medical Sciences

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Phone

+98 23 3239 5054

Email

sharrifi44_r@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Maryam Ameri

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahroud - Haft Tir Square - Shahroud University of Medical Sciences

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Phone

+98 23 3239 5054

Fax

Email

maryam19_2006@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

They will be made available with the consent of the University of Medical Sciences if the journal requires the participants' data file.

When the data will become available and for how long

three months

To whom data/document is available

Publicly available

Under which criteria data/document could be used

Data is only available for research projects or theses approved by medical universities throughout the country and only by providing a code of ethics and IRCT code.

From where data/document is obtainable

Study Guiding Professor

What processes are involved for a request to access data/document

E-mail the study guide with the ethics code and IRCT code.

Comments