Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Survey The effect of warm footbath on sleep quality in patients hospitalized in the CCU

Protocol summary

Summary

This study will perform to investigate the effect of warm footbath on sleep quality in patients hospitalized in CCU. The study is a controlled clinical trial on 120 patients who admitted in the cardiac intensive care unit. Samples will be selected from available study population and after obtaining the informed consent, they will be divided into two groups of 60 cases (intervention group and the control group). SMHSQ questionnaire of hospital sleep quality will be used in both groups to measure the sleep quality. In both groups before the intervention, SMHSQ questionnaire will be completed as base measurement. Foot baths will perform for three consecutive nights for patients in the invention group. No action will be performed in the control group. In foot bath group, the procedure will perform with 41 ° C water for 20 minutes, 50 minutes before bedtime. Legs up to 20 cm above the ankle will dip in a special plastic container. SMHSQ questionnaire will be completed every day during the 7 to 8 am. In the control group, nothing will be done in 3 consecutive nights of intervention, but The SMHSQ questionnaire will be completed for three days and each day during 7 to 8 am.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121413156N9**
Registration date: **2015-11-18, 1394/08/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-11-18, 1394/08/27

Registrant information

Name

Mohammad Ali Heydari Gorji

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1226 7342

Email address

mheydarigorji@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences.

Expected recruitment start date

2015-09-01, 1394/06/10

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey The effect of warm footbath on sleep quality in patients hospitalized in the CCU

Public title

The effect of warm footbath on sleep quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria included: age over 18 years, full consciousness, having no chronic sleep disorder, Ejection Fraction above 40% ,not under long-term treatment by sleep-inducing drugs. Exclusion criteria excluded patient fatigue, changes in patient hemodynamic, having

vascular and skin diseases, having wound or bandage below the knee area, receiving the opioid drug for less than 4 hours before the intervention.

Age
From **18 years** old to **65 years** old

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

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
Mazandaran University of Medical Sciences

Street address
Moallem Square , Sari , Mazandaran

City
Sari

Postal code
4816715793

Approval date
2015-06-22, 1394/04/01

Ethics committee reference number
IR.MAZUMS.REC.94-1524

Health conditions studied

1

Description of health condition studied
sleep

ICD-10 code
F51.2

ICD-10 code description
Nonorganic disorder of the sleep-wake schedule

Primary outcomes

1

Description
quality of sleep

Timepoint
before intervention and three consecutive days after intervention

Method of measurement
hospital sleep questionnaire SMHSQ

Secondary outcomes

1

Description
Blood pressure

Timepoint
minutes: 0,5, 10, 15 and 20 before the run And minutes: 0, 5, 10, 15 and 20 during and After the intervention

Method of measurement
Patient Monitoring Set

2

Description
Heart Rate

Timepoint
minutes: 0,5, 10, 15 and 20 before the run And minutes: 0, 5, 10, 15 and 20 during and After the intervention

Method of measurement
Patient Monitoring Set

3

Description
Core Body Temperature

Timepoint
minutes: 0,5, 10, 15 and 20 before the run And minutes: 0, 5, 10, 15 and 20 during and After the intervention

Method of measurement
Tympanic Thermometer

Intervention groups

1

Description
In intervention group, the warm Foot baths will perform for three consecutive nights for patients with 41 ° C water for 20 minutes, 50 minutes before bedtime. Legs up to 20 cm above the ankle will dip in a special plastic container. SMHSQ questionnaire will be completed every day during the 7 to 8 am

Category
Other

2

Description
In the control group, nothing will be done in 3 consecutive nights of intervention, but The SMHSQ questionnaire will be completed for three days and each day during 7 to 8 am.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Fateme Zahra Hospital
Full name of responsible person
Hassan Talebi Ghadikolaei
Street address
Pasdaran Street , Imam Square , Sari , Mazandaran
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Ahmadali Enayati
Street address
Moallem Square , Sari , Mazandaran
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Hassan Talebi Ghadikolaei
Position
Master Student of Critical Care Nursing
Other areas of specialty/work
Street address
Pasdaran street , Imam square , Sari
City
Sari
Postal code
4736131167
Phone
+98 11 3334 1596
Fax
Email
h.tghems@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Doctor Mohammadali Heydarigorji
Position
Assistant Professor, Scientific Committee
Other areas of specialty/work
Street address
Nasibeh School of Nursing and Midwifery, Vesal Shirazi Street, Sari, Mazandaran
City
Sari
Postal code
4736131167
Phone
+98 11 3379 5579
Fax
Email
heydarigorji@mazums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Hassan Talebi Ghadikolaei
Position
Master Student of Critical Care Nursing
Other areas of specialty/work
Street address
Pasdaran Street ,Sari ,Mazandaran
City
Sari
Postal code
4736131167
Phone
+98 11 3334 1596
Fax
Email
h.tghems@yahoo.com
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