

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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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

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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

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Moallem Square , Sari , Mazandaran

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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**

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Full name of responsible person

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Position

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Position

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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