

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### The effect of foot massage on the quality of sleep in patients with ischemic heart hospitalized in intensive care unit at the Ekbatan Hospital.

#### Protocol summary

##### Summary

The aim of this study was to investigate the effect of foot massage on the sleep quality of hospitalized patients with ischemic heart Ekbatan the hospital's CCU. The sample consisted of 60 patients in the experimental and control groups. Inclusion criteria included being vigilant; stay in CCU; non-vascular and clotting disorders and diabetes; are not susceptible to foot massage. Exclusion criteria included a history of chronic sleep disorder; the patient died. SMSHQ sleep quality questionnaire before massage at 9 pm and the next morning it is measured. Initially set up by the slippery lubricant gel and foot massage is given For two consecutive nights at the four stages of 10 minutes. Method: 1-While the patient's foot is on the high side Using thumb or finger pressure is between the tendons of the wrist to the finger slowly. 2-Patient's foot is worn from the heel to the toes with the thumb knob. 3-Patient toes stretched along each finger and then pulled in front and back sides of stretch to be bend. 4-The base of each finger kept between the thumb and other fingers and along each finger to tip pulled up and turned out to be.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013030912749N1**

Registration date: **2013-05-01, 1392/02/11**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-05-01, 1392/02/11

##### Registrant information

Name

Saeed Abdi

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0572

##### Email address

s.abdi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-Chancellor of Research and Technology; Hamadan University of Medical Sciences

##### Expected recruitment start date

2013-04-21, 1392/02/01

##### Expected recruitment end date

2013-07-23, 1392/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of foot massage on the quality of sleep in patients with ischemic heart hospitalized in intensive care unit at the Ekbatan Hospital.

##### Public title

The Effect of Foot Massage on Sleep in Patient with Heart disease

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Being conscious; Having a sleep quality score of at least 8; No diabetes and the risk of deep vein thrombosis; No drug and alcohol addiction; Lack of sensitivity to the massage. Exclusion criteria: Dead; Sick;

Sick leave; A history of chronic sleep disorders.

## 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: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Hamadan University of Medical Sciences

##### Street address

Shaheed Fahmideh Avenue; Hamadan University of Medical Sciences

##### City

Hamadan

##### Postal code

6517838698

#### Approval date

2012-04-09, 1391/01/21

#### Ethics committee reference number

D/P/16/35/9/48

## Health conditions studied

### 1

#### Description of health condition studied

Ischaemic Heart Diseases

#### ICD-10 code

I20-I25

#### ICD-10 code description

I20-I21-I22-I23-I24-I25

## Primary outcomes

### 1

#### Description

Quality of Sleep

#### Timepoint

Before intervention; After intervention When waking up

#### Method of measurement

SMHSQ Questionnaire

## Secondary outcomes

### 1

#### Description

Heart rate

#### Timepoint

Before Intervention; 1 minute after Intervention

#### Method of measurement

Monitoring

### 2

#### Description

blood pressure

#### Timepoint

Before Intervention; 1 minute after Intervention

#### Method of measurement

Monitoring

## Intervention groups

### 1

#### Description

Intervention group: Initially set up by the slippery lubricant gel and foot massage is given For two consecutive nights at the four stages of 10 minutes. Method: 1- While the patient's foot is on the high side Using thumb or finger pressure is between the tendons of the wrist to the finger slowly. 2- Patient's foot is worn from the heel to the toes with the thumb knob. 3- Patient toes along each finger and then pulled in front and back sides of stretch to be bend. 4- Rule of the thumb between the thumb and other fingers kept along each finger tip pulled up and turned out to be. SMSHQ sleep quality questionnaire before massage at 9 pm and the next morning it is measured.

#### Category

Other

### 2

#### Description

Control Group receives the routine Nursing Care in CCU Ward.

#### Category

Other

## Recruitment centers

1

#### Recruitment center

##### Name of recruitment center

Ekbatan Therapeutic and Education center of Hamadan

##### Full name of responsible person

Saeed Abdi

##### Street address

Taleghani Avenue; Jahad field

##### City

Hamadan

#### Sponsors / Funding sources

1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research and Technology; Hamadan University of Medical Sciences

##### Full name of responsible person

Dr Heydar Tavalani

##### Street address

Shahid Fahmide avenue

##### City

Hamadan

##### 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 and Technology; Hamadan 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

Nursing and Midwifery College; Hamadan University of medical Sciences

##### Full name of responsible person

Saeed Abdi

##### Position

Internal and Surgical Orientation; Candidate of Master of Sciences in Nursing

##### Other areas of specialty/work

##### Street address

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s.abdi@umsha.ac.ir; s.abdi007@yahoo.com

##### Web page address

#### Person responsible for scientific inquiries

##### Contact

##### Name of organization / entity

Department of Internal Medicine and Surgery, Nursing and Midwifery School

##### Full name of responsible person

Dr Khodayar Oshvandi

##### Position

PhD

##### Other areas of specialty/work

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#### Person responsible for updating data

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##### Name of organization / entity

Nursing and Midwifery College; Hamadan University of Medical Sciences

##### Full name of responsible person

Saeed Abdi

##### Position

Internal and Surgical Orientation; Candidate of Master of Sciences in Nursing

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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*