# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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)

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**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 Tavilani
**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
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## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Department of Internal Medicine and Surgery, Nursing and Midwifery School
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## Person responsible for updating data

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**Full name of responsible person**
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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*