

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The comparison of the effect of massage and elevation on decreasing hand edema of patients of intensive care units of Kerman city medical sciences university

Protocol summary

Summary

Objective: The edema is an important complication of bed rest in intensive care units (ICU). The aim of this study is comparison of effect of massage and elevation on decreasing hand edema of these patients. Design: It is a randomize and double blind study. Setting and conduct: In this study, there are 35 patients of ICU with inclusion criterias that include: having pitting edema at least 2 mm or +1 grade according pitting scale ; comatose patients with maximum level 8 of Glasgow Coma Scale (GCS). Exclusion criterias include: having subclavian catheter; edema after mastectomy; heart failure; hepatic or renal disease; present of thromboembolism, infection and wound or fracture and amputation in one or both of hands. Intervention: In this study, before the intervention, the researcher measure and record circumference of wrist and middle of arm by a meter (milimeter), then one of the hand is placed in the Intermittent Pneumatic Compression (IPC) device by a nurse and receive massage with 50 mmHg. The other hand is elevated by a slope board with 30 degree for 30 minutes. After this time, the researcher measure circumference of hand again for checking the changes in size to compare which method is more effective. This intervention perform two times in a day between 8-12 AM and 4-7 PM, in whole five sessions for every patient. main outcome: Hand edema

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307155426N6**
Registration date: **2013-08-03, 1392/05/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-03, 1392/05/12

Registrant information

Name

Mehdi Ahmadinejad

Name of organization / entity

Anesthesiology department, Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 0223 5011

Email address

m.ahmadinejad@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Kerman University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of massage and elevation on decreasing hand edema of patients of intensive care units of Kerman city medical sciences university

Public title

The comparison of the effect of massage and elevation on decreasing hand edema of patients of intensive care units of Kerman city medical sciences university

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: having pitting edema at least 2 mm or +1 grade according to pitting scale; comatose patients with maximum level 8 of Glasgow Coma Scale (GCS). Exclusion criteria include: having subclavian catheter; edema after mastectomy; heart failure; hepatic or renal disease; present of thromboembolism, infection and wound or fracture and amputation in one or both of hands.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 35

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice chancellor for research of Kerman University of Medical Sciences

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jihad Blvd, Somayye Crossroads, Shariati St, Kerman

City

Kerman

Postal code**Approval date**

2013-07-20, 1392/04/29

Ethics committee reference number

179/92/5

Health conditions studied**1****Description of health condition studied**

Edema

ICD-10 code

E43

ICD-10 code description

Unspecified severe protein-energy malnutrition

Primary outcomes**1****Description**

Hand edema

Timepoint

Immediately before and after every intervention

Method of measurement

With meter and according to millimeter

Secondary outcomes**1****Description**

central venous pressure

Timepoint

Immediately before and after every intervention

Method of measurement

with central venous pressure ruler according to CmH₂O

Intervention groups**1****Description**

Intervention one: The researcher measure circumference of wrist and middle of arm by a meter (millimeter), then the hand is elevated by a slope board with 30 degree for 30 minutes. After this time, the researcher measure circumference of hand again for checking the changes in size.

Category

Prevention

2**Description**

Intervention two: The researcher measure and record circumference of wrist and middle of arm by a meter (millimeter), then the hand is placed in the Intermittent Pneumatic Compression (IPC) device by a nurse and receive massage with 50 mmHg. After this time, the researcher measure circumference of hand again for checking the changes in size.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital

Full name of responsible person

Dr Mehdi Ahmadinejad

Street address

Shahid Bahonar Hospital, Qarani St, Valiasr
Crossroads, Shariaati St, Kerman

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Kerman University of
Medical Sciences

Full name of responsible person

Dr. Reza Malekpour Afshar

Street address

Vice chancellor for research, Kerman University of
Medical Sciences, Jahad Blvd, Somayye Crossroads,
Shariaati St, Kerman

City

Kerman

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 Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Dr Mehdi Ahmadi Nejad

Position

Fellow in Critical Care Assistant professor

Other areas of specialty/work**Street address**

Shahid Bahonar Hospital, Qarani St, Valiasr
Crossroads, Shariaati St, Kerman

City

Kerman

Postal code**Phone**

+98 34 1223 5011

Fax**Email**

mehdia50@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Mehdi Ahmadi Nejad

Position

Fellow in Critical Care/ Assistant professor

Other areas of specialty/work**Street address**

Shahid Bahonar Hospital, Qarani St, Valiasr
Crossroads, Shariaati St, Kerman

City

Kerman

Postal code**Phone**

+98 34 1223 5011

Fax**Email**

mehdia50@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Mehdi Ahmadi Nejad

Position

Fellow in Critical Care/ Assistant professor

Other areas of specialty/work**Street address**

Shahid Bahonar Hospital, Qarani St, Valiasr
Crossroads, Shariaati St, Kerman

City

Kerman

Postal code

7619643797

Phone

+98 34 1223 5011

Fax

+98 34 1226 0100

Email

mehdia50@gmail.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