

# 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 criterias: 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.

### **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, Shariaati St, Kerman

##### **City**

kerman

##### **Postal code**

#### **Approval date**

2013-07-20, 1392/04/29

#### **Ethics committee reference number**

179/92/15

## **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 milimeter

## **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**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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*