

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The study of the effect of duration of foot massage time on physiological indices of cerebrovascular accident patients with a lack of consciousness hospitalized in intensive care units

Protocol summary

Study aim

The study of the effect of duration of foot massage time on physiological indices of cerebrovascular accident patients with a lack of consciousness hospitalized in intensive care units

Design

A clinical trial with two parallel intervention groups: one-blind, randomized, quadruple blocks with 64 samples

Settings and conduct

This study is performed on patients with cerebrovascular accidents with decreased consciousness in the intensive care units of Imam Reza, Farabi, and Taleghani Hospitals of Kermanshah University of Medical Sciences. In the first intervention group 5 minutes, and in the second intervention group 10 minutes of massage of the foot will be carried out. Then, changes in the physiological indices are compared in two groups. The study is one-blind and as for lack of consciousness in participant patients in the study, without knowing the duration of massage time which is done for them, are divided into two groups of 5 and 10 minutes massage.

Participants/Inclusion and exclusion criteria

Entry requirements include: admission in the intensive care unit due to stroke, passing 48 hours after the initial admission, GCS score less than 15, passing at least 6 hours from receiving opiate and sedation medications; No entry conditions include: suffering from coagulation and vascular disorders in the legs, diabetes and dysrhythmia, fractures and /or amputations in the lower extremities, having wounds, infection or skin disease, receiving drugs that affect blood pressure and heart rate

Intervention groups

In the first intervention group, foot massage is performed for 5 minutes and in the second intervention group, the foot massage is performed for 10 minutes.

Main outcome variables

Changes in physiological indices of patients with

cerebrovascular accidents by decreasing the level of consciousness admitted to the intensive care unit regarding the duration of massage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180110038292N1**

Registration date: **2018-05-06, 1397/02/16**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-06, 1397/02/16**

Update count: **0**

Registration date

2018-05-06, 1397/02/16

Registrant information

Name

Sara Poorshadan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 6301

Email address

s.poorshadan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-04, 1396/11/15

Expected recruitment end date

2018-06-05, 1397/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effect of duration of foot massage time on physiological indices of cerebrovascular accident patients with a lack of consciousness hospitalized in intensive care units

Public title

The effect of duration of foot massage time on physiological indices

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Admission in the intensive care unit due to stroke Pass 48 hours after patients hospitalization passing at least 6 hours from receiving opiate and sedation medications GCS score less than 15

Exclusion criteria:

Coagulation and vascular disorders in the legs, diabetes and dysrhythmia Fracture or amputation lower limb Having sore, infection or skin disease in the legs Receiving drugs that affect blood pressure and heart rate

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization algorithm is performed using Smith's method. By using randomized blocks method (four blocks of letters A and B), eligible samples are assigned to two intervention groups. The randomization tool consists of some cards which have a combinations of two letters A and two letters B. These combinations are then randomly selected each time to determine how the four samples are placed in each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

As for lack of consciousness in participant patients in the study, without knowing the duration of massage time which is done for them, are divided into two groups of 5 and 10 minutes massage.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No. 2 of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Approval date

2018-02-28, 1396/12/09

Ethics committee reference number

IR.KUMS.REC.1396.652

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

Patients with cerebrovascular accidents and with decreased consciousness

ICD-10 code

VI

ICD-10 code description

Diseases of the nervous system

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

Changes in physiological indices of patients with cerebrovascular accidents and decreased consciousness

Timepoint

2 minutes before the massage, 1 minute after the massage, 5 minutes after the massage

Method of measurement

The monitor used in Intensive Care Unit and a mercury thermometer

Secondary outcomes

empty

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

The first intervention group: cerebrovascular accident

patients with a lack of consciousness hospitalized in intensive care unit receives foot massage for 5 minutes.

Category

Other

2

Description

The second intervention group: cerebrovascular accident patients with a lack of consciousness hospitalized in intensive care unit receives foot massage for 10 minutes.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Ali Soroush

Street address

Sorkhe Lyzheh Ave

City

Kermanshah

Province

Kermanshah

Postal code

6714415333

Phone

+98 83 3427 6301

Email

s.poorshadan@gmail.com

Web page address

2

Recruitment center

Name of recruitment center

Farabi hospital

Full name of responsible person

Jalal Shakeri

Street address

Dolat Abad Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3826 0700

Email

s.poorshadan@gmail.com

3

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Khosrow Farhadi

Street address

Shahid Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6715847167

Phone

+98 83 3836 7989

Email

s.poorshadan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Kermanshah University of Medical Sciences, Shahid Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Phone

+98 83 3838 4185

Email

s.poorshadan@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Sara Poorshadan

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 71, 221 Ave, Gozarname Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714689849

Phone

+98 83 3427 6301

Fax**Email**

s.poorshadan@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Sara Poorshadan

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 71, 221 Ave, Gozarname Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714689849

Phone

+98 83 3427 6301

Fax**Email**

s.poorshadan@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Sara Poorshadan

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No 71, 221 Ave, Gozarname Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714689849

Phone

+98 83 3427 6301

Fax**Email**

s.poorshadan@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available