

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The short time foot massage effect evaluation on physiological indices in neurosurgical patients in intensive care units.

Protocol summary

Summary

The goal of this study is evaluation of short time foot massage on vital signs of neurosurgical patients. The study population includes patients who had neurosurgical operations and hospitalized in critical care units. The sample is 78, 39 on case group and 39 on control. Inclusion criteria: 1- Hospitalization on ICU; 2- The cause of hospitalization is exposure to neurosurgery; 3- Lack of acute orthopedic disorders in feet; 4- Having plantar reflex; 5- Vigilance level between 8 to 15. Exclusion criteria: 1- appearance of feet vascular disorders; 2- Continuous infusion of opioid and non-opioid painkillers; 3- appearance of skin disorders on ankle. The effect of foot massage on both feet at 5 minutes will be evaluated and the primary outcome is the patient's vital signs, including reduced stress.

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Recruitment status

Recruitment complete

Funding source

Kermanshah university of medical sciences

Expected recruitment start date

2012-11-05, 1391/08/15

Expected recruitment end date

2013-01-04, 1391/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012081110560N1**

Registration date: **2012-12-24, 1391/10/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-24, 1391/10/04

Registrant information

Name

Hiva Azami

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

Scientific title

The short time foot massage effect evaluation on physiological indices in neurosurgical patients in intensive care units.

Public title

the effect of massage on patient vital signs

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1- Hospitalization on ICU; 2- The cause of hospitalization is exposure to neurosurgery; 3- Lack of acute orthopedic disorders in feet; 4- Having plantar reflex; 5- Vigilance level between 8 to 15; 6- absence of neuro muscular disorder, MS, guilen bareths and; 7- absence of diabetes mellitus. Exclusion criteria: 1- appearance of feet vascular disorders; 2- Continuous infusion of opioid and non-opioid painkillers; 4- DVT; 5- appearance of delirium because of non cooperation; 6- appearance of DIC; 7- appearance cardiac disorders that affects vital sings; 8- appearance cardiac disorders that needs medication infusion that affects heart rate.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 78

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah university of medical sciences

Street address

Building Number 2, Kermanshah university of medical sciences

City

kermanshah

Postal code

Approval date

2012-11-04, 1391/08/14

Ethics committee reference number

7/420/35277/پ

Health conditions studied

1

Description of health condition studied

intra cranial contusion

ICD-10 code

s06.3

ICD-10 code description

Focal brain injury Focal: cerebral: contusion laceration
traumatic intracerebral haemorrhage

2

Description of health condition studied

epidural hematoma

ICD-10 code

s06.4

ICD-10 code description

Extradural haemorrhage (traumatic)

3

Description of health condition studied

sub dural hematoma

ICD-10 code

s06.5

ICD-10 code description

Traumatic subdural haemorrhage

4

Description of health condition studied

sub arachnoid hematoma

ICD-10 code

s06.6

ICD-10 code description

Traumatic subarachnoid haemorrhage

5

Description of health condition studied

intra cranial injury

ICD-10 code

s06.7

ICD-10 code description

Intracranial injury with prolonged coma

Primary outcomes

1

Description

heart rate

Timepoint

minutes 1 and 5 before and after massage

Method of measurement

monitoring

2

Description

respiratory rate

Timepoint

minutes 1 and 5 before and after massage

Method of measurement

monitoring

3

Description

blood pressure

Timepoint

minutes 1 and 5 before and after massage

Method of measurement

electronit tympanic thermometer

4

Description

temprature

Timepoint

minutes 1 and 5 before and after massage

Method of measurement

electronit tympanic thermometer

5**Description**

o2 saturation

Timepoint

minutes 1 and 5 before and after massage

Method of measurement

puls oxymeter tool

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

anxiety

Timepoint

before and after massage

Method of measurement

by monitoring vital signs and symptoms

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

The steps of massage are, positioning the patient in semisetting position. implementing the pillow under the patients feet and after lubricating the practitioners hands with baby oil the massage in 4 steps will start: 1- Cleaning between the tendons 2- Rubbing the feet 3- Lifting the toes 4- Pinching toes. after doing that steps. Those steps will use for the other foot. Then immediately for 5 minutes the vital signs will be measured (in times 1 and 5).

Category

Other

2**Description**

In group control, simultaneously with case group we measure the vital sings of the patients in minutes 1 and 5 before massage in intervention group and minutes 1 and 5 after massage in intervention group.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam reza hospital

Full name of responsible person**Street address****City**

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University Of Medical Sciences

Full name of responsible person

Dr Reza Khoda rahmi

Street address

Building Number 2; Kermanshah University Of Medical Sciences

City

Kermanshah

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

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**

kermanshah university of medical sciences, nursing faculty

Full name of responsible person

Hiva Azami

Position

student of m. sc of nursing critical care

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

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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