Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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.

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

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Name of organization / entity

Kermanshah University of Medical Sciences

Country

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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

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
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student of m. sc of nursing critical care
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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