

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of foot massage on pain severity in unconscious patients during change position in intensive care unit

Protocol summary

Summary

Objective: The aim of this study is to evaluate the effect of massage on pain intensity in patients with change of position. Design: This study is a randomized clinical trial with two groups before -after design. Setting and conduct: This study will be conducted with participation of 80 patients with decreased level of consciousness. Each group consisted of 40 peoples. Inclusion criteria: age between 18-60 years old; ability to respond to painful stimulation; having pain during change positions; doesn't have diabetes, DVT, alcohol abuse, drug addiction, and skin problems. Exclusion criteria: increase level of consciousness; starting continuous infusion of sedative and analgesic agents; the occurrence of a serious event for the patient. Intervention: subjects will be selected by random sampling method and will be divided into two groups: a routine care group, and foot massage group. In the both groups, immediately after changed position, the pain intensity of the patients will be measured by using of observational pain assessment tool, and then 20 minutes before change position massage techniques will be applied. Massage will be done with slow movements of the ankle to the bottom, again, after second change of position, the pain intensity will be measured right after and 10 minutes after the massage. Control group will not receive any treatment. Main outcome measure: The main outcome will be the pain severity due to change of position of patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121031327N1**

Registration date: **2017-04-10, 1396/01/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-10, 1396/01/21

Registrant information

Name

Zahra Veladati

Name of organization / entity

Hamadan University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences

Expected recruitment start date

2017-02-28, 1395/12/10

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot massage on pain severity in unconscious patients during change position in intensive care unit

Public title

The effect of massage on pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 18-60 years old; patients with a decreased level of consciousness by GCS between 5 and 8, that unable to verbal and non-verbal communication; the patients didn't use any muscle relaxant drugs; at least for 24 hours unable to express their pain; ability to respond to painful stimulation; having pain during change positions; doesn't have diabetes, DVT, alcohol abuse, drug addiction, and skin problems. Exclusion criteria: increase level of consciousness; starting continuous infusion of sedative and analgesic agents; the occurrence of a serious event for the patient.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Ethics Committee of Hamedan University of Medical Science

Street address

Hamadan University of Medical Science, Shahid Fahmide boulevard, Hamadan

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Postal code

009881338380717

Approval date

2016-07-16, 1395/04/26

Ethics committee reference number

IR.UMSHA.REC.1395.218

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R52.9

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

pain

Timepoint

Before intervention. Immediately after the intervention.
Ten minutes after intervention

Method of measurement

Critical Care Pain Observation Tool (CPOT)

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, foot massage will be done from the ankle to the bottom for each patient for 20 minutes before changing position.

Category

Prevention

2

Description

The control group will not receive any treatments.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan Besat Hospital

Full name of responsible person

Zahra Veladati

Street address

Hamadan Besat hospital, Shahid Motahari avenue, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of
Hamadan University of Medical Science

Full name of responsible person

Saeid Bashirian

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Hamadan University of Medical Science, Shahid
Fahmide boulevard, Hamadan

City

Hamadan

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 and Technology of
Hamadan University of Medical Science

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

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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