

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Study of effect of foot massage by nurse and patient's family on delirium, pain, and some physiological parameters of patients in intensive care units

Protocol summary

Summary

Aim: This study aimed to investigate the effect of massage therapy on delirium, pain, and some physiological parameters of patients in intensive care units of shahid Bamonar Hospital of Kerman city. Design: Clinical trial with random allocation of patients in two groups of intervention (nursing and family massage) and control group. Participants: 63 patients in intensive care units are introduced to the study based on the inclusions and exclusions criteria. Intervention: Patients in intervention groups will receive massage therapy and the control group receive usual care of treatment center. Outcome: Evaluation of delirium, pain, and some physiological parameters and the effectiveness of massage therapy, in the three groups, before of the intervention, 30 minutes after of the intervention (6 day) and one week after of the intervention (day 13)

General information

Acronym

Not used

IRCT registration information

IRCT registration number: **IRCT201707317844N12**

Registration date: **2017-08-29, 1396/06/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-29, 1396/06/07

Registrant information

Name

Mansour Arab

Name of organization / entity

Kerman University of Medical Sciences

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Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of effect of foot massage by nurse and patient's family on delirium, pain, and some physiological parameters of patients in intensive care units

Public title

effect of foot massage on delirium, pain, and some physiological parameters of patients in intensive care units

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with tracheal tube or tracheostomy, (GCS) (9-11) in patients with tracheal tube and tracheostomy, lack of continuous infusion of sedative drugs such as midazolam and propofol, lack of continuous infusion of narcotics such as fentanyl, no

history of mental disorders such as Psychosis and mental retardation, knowledge of Farsi, able to co-operate in the field of vision and hearing, ages 50-15, Absence of Withdrawal syndrome, not having foot vascular disorders such as DVT with doctor's diagnosis, no fractures in the lower limbs, lack of Skin disease, ulcers and foot infections. Exclusion criteria: loss of consciousness less than 9, extubation, death of the patient, discharge, skin diseases such as ulcers and infections of feet, Suffering from vascular disorders such as DVT

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The random allocation method is stratified random allocation

Secondary Ids**1****Registry name**

Not used

Secondary trial Id

Not used

Registration date

empty

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

Ethics Committee of Kerman University of Medical Science

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jahad Blvd, Somayye Crossroads, Shariaati St, Kerman

City

kerman

Postal code

Not used

Approval date

2017-07-30, 1396/05/08

Ethics committee reference number

ir.kmu.rec.1396.1460

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

physiological parameters

ICD-10 code

(R00-R09)

ICD-10 code description

R00.0/R00.1/R03.0/R03.1/R06.4/R06.8

2**Description of health condition studied**

delirium

ICD-10 code

F05

ICD-10 code description

F05.9/F05.8

3**Description of health condition studied**

pain

ICD-10 code

R52

ICD-10 code description

R52.0/R52.2

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

delirium

Timepoint

before of the intervention, 30 minutes after of the intervention (6 day) and one week after of the intervention (day 13)

Method of measurement

CAMICU tool

2**Description**

pain

Timepoint

before of the intervention, 30 minutes after of the intervention (6 day) and one week after of the intervention (day 13)

Method of measurement

Behavioral Scale of Pain (BPS)

3**Description**

physiological parameters

Timepoint

before of the intervention, 30 minutes after of the intervention (6 day) and one week after of the intervention (day 13)

Method of measurement

Using of monitored device

Secondary outcomes

empty

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

Control group: No action

Category

Treatment - Other

2**Description**

Intervention group 1: Foot Swedish massage is given by nurse for six days, once a day, and every leg for 5 minutes.

Category

Treatment - Other

3**Description**

Intervention group 2: Foot Swedish massage is given by patient's family for six days, once a day, and every leg for 5 minutes.

Category

Treatment - Other

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

shahid Bahonar Hospital of Kerman city

Full name of responsible person**Street address**

shahid Bahonar Hospital of Kerman city

City

Kerman

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

investigator

Full name of responsible person

maasome momeni

Street address

Kerman

City

Kerman

Grant name

ندارد

Grant code / Reference number

Not used

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

Yes

Title of funding source

investigator

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**

Razi Nursing and Midwifery School

Full name of responsible person

Mansour Arab

Position

MSN/ Lecturer of Nursing

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

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Person responsible for updating data

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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