

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of massage therapy on restlessness of patients undergoing mechanical ventilation in ICU

Protocol summary

Study aim

evaluate the effect of massage therapy on restlessness of patients undergoing mechanical ventilation in ICU

Design

The study will be conducted as a clinical trial in the ICU of Namazi Hospital affiliated to Shiraz University of Medical Sciences from October to December 2017 and on 40 patients in pilot form in order to calculate the final sample size after data collection. Eligible patients enter the study after obtaining informed consent. Sampling is done easily and patients are randomly assigned to groups. The restlessness of patients is calculated by Richmond Agitation-Sedation Scale (RASS).

Settings and conduct

ICU of Namazi Hospital affiliated to Shiraz University of Medical Sciences. In the intervention group, therapeutic massages will be performed with the Thai classical method using sweet almond oil. Back, shoulders, deltoid muscles, arms, forearms, palms and fingers and toes, posterior and front parts of thighs, posterior and front parts of shins, back of the legs, abdomen, armpits and neck muscles of the patient will be massaged for 20 minutes in the morning and in the evening. By cutting off the sedatives, the restlessness-sedation score will be evaluated and recorded based on the RASS criteria, 30 minutes before the intervention, 60 and 120 minutes after the intervention.

Participants/Inclusion and exclusion criteria

Restless patients undergoing mechanical ventilation in intensive care units

Intervention groups

therapeutic massages will be performed with the Thai classical method using sweet almond oil. control group: receives routine care

Main outcome variables

patient's agitat. need for sedative medications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111224008505N46**

Registration date: **2018-04-02, 1397/01/13**

Registration timing: **retrospective**

Last update: **2018-04-02, 1397/01/13**

Update count: **0**

Registration date

2018-04-02, 1397/01/13

Registrant information

Name

Seyed Saeed Najafi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1727 7445

Email address

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of massage therapy on restlessness of patients undergoing mechanical ventilation in ICU

Public title

The effect of massage therapy on restlessness of patients undergoing mechanical ventilation in ICU

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction of the first-degree relatives to participate in the study; ages 18 and older intact massager areas getting permission from the physician, Glasgow scale score of 5 or higher lack of addiction to drugs or alcohol 24 hours after hospitalization in the ICU hemodynamic stability mechanical ventilation for at least 48 hours the absence of infectious diseases, hepatitis and known skin problems lack of dialysis fistula and history of fracture in the last 2 months (to prevent damage to the limbs) no limitation for body changes (such as acute bleeding, floating chest) or massage (such as severe burns, severe shortness of breath, fever, etc.) restlessness behavior in the range of +1 to +4 according to the Richmond criterion

Exclusion criteria:

Significant reduction in consciousness wounds in massager areas quadriplegia receiving neuromuscular restraints extubation earlier than 48 hours loss of restlessness after the first intervention, and lack of restlessness for subsequent interventions patients with known venous thrombosis (for the prevention of embolism) limb amputation due to sensory impairment patient for whom the dialysis fistula is inserted or who have fracture

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is done easily and patients are randomly assigned to groups. This study is a randomized reverse block method.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome of the investigation is that the person under investigation is not aware of any intervention or that the person is intervening.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz, 7th floor, Shiity of Medical Sciencraz Universes, Zand Blvd.,

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Postal code

71348-14336

Approval date

2017-07-19, 1396/04/28

Ethics committee reference number

IR.SUMS.REC.1396.73

Health conditions studied

1

Description of health condition studied

Agitation

ICD-10 code

R46

ICD-10 code description

symptoms and sings involving appearance and behaviour

Primary outcomes

1

Description

agitation

Timepoint

30 minutes before the intervention, 60 and 120 minutes after the intervention.

Method of measurement

Richmond Agitation-Sedation Scale (RASS)

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: therapeutic massages will be performed with the Thai classical method using sweet almond oil. the patient will be massaged for 20 minutes in the morning and in the evening.

Category

Lifestyle

2**Description**

Control group: receives routine care

Category

Lifestyle

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

Nemazee Hospital-shiraz

Full name of responsible person

Effat Zarifinezhad

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

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Seyed saeed najafi

Position

Instructor faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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

Shiraz University of Medical Sciences

Full name of responsible person

Effat Zarifinezhad

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B.A

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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