Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Hospitalaffiliated 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

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Iran (Islamic Republic of)

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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 massage 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 massage areas quadriplegia receiving neuromuscular restrainters 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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Fars

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
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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
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Position
Instructor faculty member

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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