

# 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

najafisa@sums.ac.ir

##### 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.,

##### City

Shiraz

##### Province

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 signs 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

**Street address**

Shiraz. Karim Khan Zand Boulevard- Nemazee Hospital

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**Phone****Fax****Email**

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Sayed Baser Hashemi

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hashemib@sums.ac.ir

**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

**Street address**

School of Nursing and Midwifery, Namazi Square, Shiraz, Iran

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Sayed Said najafi

**Position**

Master of Nursing

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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Shiraz University of Medical Sciences

**Full name of responsible person**

Effat Zarifinezhad

**Position**

B.A

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Dormitory of Medical Sciences

**City**

Shiraz

**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