

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of foot reflexology massage on pain and anxiety of suctioning of patients under mechanical ventilation

Protocol summary

Study aim

Determining the effect of reflexology foot massage on pain and anxiety caused by suction in hospitalized patients

Design

A clinical trial with a control group, single, randomized groups, on 36 patients, a simple randomization method was used for randomization.

Settings and conduct

Many studies around the world have been conducted to investigate the effect of foot reflexology massage on pain and anxiety. In this study, the effect of foot reflexology massage on pain and anxiety caused by suction in mechanically ventilated patients was investigated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Being hospitalized for at least 24 hours 2- The patient is under mechanical ventilation and needs suction. 3- Do not use sedatives and anti-anxiety drugs at least three hours before and during suction. 4- GCS above 5- Do not hit the head. Exclusion criteria: 1- The need for other therapeutic intervention during the study 2- Awakening and sudden exit of the endotracheal tube 3. Disorder in the patient's hemodynamic status during the study

Intervention groups

In the intervention group, foot reflexology massage is performed by a trained person for 10 minutes for each foot and a total of 20 minutes for both feet. The patient's level of anxiety and pain is measured once immediately after the suction and before the start of the foot reflexology massage based on the available questionnaires, and one time after the end of the 20-minute foot reflexology massage. In the control group, foot reflexology massage is not performed and the patient's pain and anxiety level are measured once immediately after suction and once after 20 minutes.

Main outcome variables

pain; anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210331050800N1**

Registration date: **2021-04-26, 1400/02/06**

Registration timing: **retrospective**

Last update: **2021-04-26, 1400/02/06**

Update count: **0**

Registration date

2021-04-26, 1400/02/06

Registrant information

Name

negin mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8871 6788

Email address

neginm137@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology massage on pain and anxiety of suctioning of patients under mechanical ventilation

Public title

The effect of foot reflexology massage on pain and anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalization for at least 24 hours The patient is under mechanical ventilation and needs suction. Stability of hemodynamic status (blood pressure (140-100 mm Hg) - heart rate (60-100) - respiration rate (12-12) - SPO2 (90% or higher)) Do not use sedatives and anti-anxiety drugs at least three hours before and during suctioning. Patient age over 18 years and less than 75 years GCS above 8 The patient is not addicted to alcohol, drugs and cigarettes. The health of the soles of the feet has been confirmed in the absence of corns, fungal skin problems, previous scars, and neuropathy. Do not hit the head.

Exclusion criteria:

Need to perform other therapeutic interventions while studying Awakening and sudden exit of the endotracheal tube Impaired hemodynamic status of the patient during the study

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done by available method and based on inclusion criteria. Randomization is done by simple random method and by lottery method. Write the word test on one sheet of paper and the word control on another sheet of paper and place it in a container. Draw for the first patient to determine if they are in the test or control group. For example, if the first person is in the test group, the next patient will be in the control group or vice versa. And so the rest of the samples are taken.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of aja university of medical sciences

Street address

Shariati St., Kaj St., Molly Al-Movahedin
Organizational Alley

City

Tehran

Province

Tehran

Postal code

1613917111

Approval date

2021-03-02, 1399/12/12

Ethics committee reference number

IR.AJAUMS.REC.1399.247

Health conditions studied

1

Description of health condition studied

The effect of foot reflexology massage on pain and anxiety caused by suction in mechanically ventilated patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score obtained based on COPT instrument

Timepoint

Pain measurement immediately after suction (before intervention) and after 20 minutes of reflexology foot massage

Method of measurement

COPT tool

2

Description

Anxiety score obtained based on FAS instrument

Timepoint

Anxiety measurement immediately after suction (before intervention) and after 20 minutes of reflexology foot massage

Method of measurement

FAS tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Reflexive foot massage is performed for 10 minutes for each foot (20 minutes in total).

Category

Other

2

Description

Control group: There is no intervention in this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان خانواده

Full name of responsible person

نگین مهرابی

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mojtaba Yousefi Zashk

Street address

نوشتار مبدأ چهار راه فاطمی، خیابان اعتمادزاده
آیا منظور شما این است: چهارراه فاطمی، auto_awesome
Fatemi crossroads، خیابان اعتمادزاده 33 / 5000 نتایج ترجمه
Etemadzadeh street

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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

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Negin Mehrabi

Position

Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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City**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

No - There is not 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