Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 pationt 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
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نوشتار مبدأ چهار راه فاطمی، خیابان اعتمادزاده
آیا منظور شما این است: چهارراه فاطمی، auto_awesome
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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
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Other areas of specialty/work
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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
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