Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of acupressure therapy on anxiety, agitation and physiologic parameters in patients weaning from mechanical ventilation

Protocol summary

Study aim

The aim of this study is to assess the effect of acupressure on anxiety, agitation, respiratory and physiologic parameters in patients during weaning of mechanically ventilation in the intensive care unit.

Design

Samples will be chosen from the patients admitted to Bu-Ali Sina hospital affiliated with Qazvin University of Medical Sciences. In this randomized controlled clinical trial, 80 patients will be randomly assigned to the experiment and control groups. The patients will be blinded to the study.

Settings and conduct

This study will be done in intensive care unit of Bu-Ali Sina hospital of Medical Science University in Qazvin city.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Four score ≥ 9;Richmond from +2 to -2; PaO2 ≥ 60 mmHg ، ABG: FiO2 ≤ 40%، PaO2 ≥ 60 mmHg, 25≥ RR); age over 18 ; Patient intubated for past 48 hours; Are on ventilation with SIMV ،PSV mode; Hemoglobin ≥ 8 mg/dl ; Without malformation or grazes in pressure points ; Haveing no psychiatric illness ; Haveing no neuromuscular illness ; Haveing no active heart disease ; Haveing no neurologic disorder that affect on respiratory ; taking no psychiatric agent ; taking no neuromuscular blocker agent; taking no sedative during past 4 hours; PTT≤60) . Exclusion criteria: Patient with no cooperation up to the end of study; Weaning of mechanical ventilation; Death of patient during the study; Daley of weaning process.

Intervention groups

Deep pressure in the experiment group and touch in the control group will perform at 5- acupoints on both sides of the body. The intervention will be carried out 20 minutes before weaning of mechanical ventilation by an educated person. The 5- acupoints include Zhongfu (Lu1), Taiyuan (Lu9), Hegu (Li4), Neiguan (Pc6) and Zusanli (St36). This technique is performed on one side of the body and then the other side of the body based on the patient's condition. Anxiety, agitation and oxygen saturation and the effect of anxiety on physiologic parameters including blood pressure, heart rate, oxygen saturation and respiratory indexes before the intervention, immediately after the intervention, under T-piece, 20 min after T-piece will be measured.

Main outcome variables

Anxiety, agitation, blood gases are measured and also the effects of anxiety on physiologic parameters including blood pressure, heart rate, Oxygen saturation of arterial blood and respiratory indexes before intervention, immediately after intervention, under T-Piece, 20 min after T-Piece.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110912007529N16**
Registration date: **2017-12-27, 1396/10/06**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-27, 1396/10/06**
Update count: **0**

Registration date

2017-12-27, 1396/10/06

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

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Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source
Shahed University Vice chancellor for research

Expected recruitment start date
2017-11-22, 1396/09/01

Expected recruitment end date
2018-05-22, 1397/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of acupressure therapy on anxiety, agitation and physiologic parameters in patients weaning from mechanical ventilation

Public title
Effects of acupressure therapy on patients weaning from mechanical ventilation

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Four score ≥ 9 Richmond score from +2 to -2 PaO2 ≥ 60 mmHg ، ABG: FiO2 ≤ 40%، PaO2 ≥ 60 mmHg, 25≥ RR) age over 18 being intubated during past 48 hours being on ventilation with SIMV and PSV mode Hemoglobin ≥ 8 mg/dl Absence of malformation or grazes in pressure points Absence of psychiatric illness Absence of neuromuscular illness Absence of active heart disease Absence of neurologic disorder that affects respiratory not taking any psychiatric agent not taking any neuromuscular blocker agent not taking sedative during past 4 hours absence of coagulation disturbance (PTT≤60)

Exclusion criteria:
Exclusion criteria :Patient with no cooperation to end of study ; Weaning of mechanical ventilation ; Death of patient during the study ; Daley of weaning process.

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients will be randomly assigned into two groups using permuted block randomization , Random numbers table will be used, Random allocation sequence will be determined using a computerized program.Opaque sealed sequentially numbered envelopes from number 1 to 80 will be used for allocation concealment

Blinding (investigator's opinion)
Double blinded

Blinding description
patients will be unaware of the groups’assignments.staff nurses in the ICU and the statistical analyzer will be blind to patients’allocation of the groups.

Placebo
Used

Assignment
Parallel

Other design features
Eligible patients will be selected through convenience sampling and will be randomly assigned into 2 groups using permuted block randomization with allocation ratio of 1:1. Random allocation sequence will be determined using a computerized program. Opaque sealed sequentially numbered envelopes from number 1 to 80 will be used for allocation concealment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahed University

Street address
Shahed University, Opposite the Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran.

City
Tehran

Province
Tehran

Postal code
3319118651

Approval date
2017-11-06, 1396/08/15

Ethics committee reference number
Shahed.REC.1396.51

Health conditions studied

1

Description of health condition studied
Patients with impaired respiratory function in ICU

ICD-10 code
J95 , J96

ICD-10 code description
Other diseases of the respiratory system

Primary outcomes

1

Description
Anxiety
Timepoint
before intervention, immediately after intervention, under T-Piece, 20 min after T-Piece.
Method of measurement
by Faces anxiety scale

2

Description
Agitation
Timepoint
before intervention, immediately after intervention, under T-Piece, 20 min after T-Piece.
Method of measurement
Richmond Scale

Secondary outcomes

1

Description
Heart rate
Timepoint
Before intervention, immediately after intervention, under T-Piece, 20 min after T-Piece
Method of measurement
Monitoring system

2

Description
Respiratory rate
Timepoint
Before intervention, immediately after intervention, under T-Piece, 20 min after T-Piece
Method of measurement
Ventilator system

3

Description
Oxygen saturation of arterial blood (SPo2)
Timepoint
Before intervention, immediately after intervention, under T-Piece, 20 min after T-Piece
Method of measurement
Pulsoximeter

4

Description
Heart rate
Timepoint
Before intervention, immediately after intervention, under T-Piece, 20 min after T-Piece
Method of measurement
Monitoring system

5

Description
Systolic Blood pressure
Timepoint
Before intervention, immediately after intervention, under T-Piece, 20 min after T-Piece
Method of measurement
Monitoring system

6

Description
Diastolic blood pressure
Timepoint
Before intervention, immediately after intervention, under T-Piece, 20 min after T-Piece
Method of measurement
Monitoring system

7

Description
Mean blood pressure
Timepoint
Before intervention, immediately after intervention, under T-Piece, 20 min after T-Piece
Method of measurement
Monitoring system

8

Description
Tidal Volume
Timepoint
Before intervention, immediately after intervention, under T-Piece, 20 min after T-Piece
Method of measurement
Monitoring system

9

Description
minute Ventilation
Timepoint
Before intervention, immediately after intervention, under T-Piece, 20 min after T-Piece
Method of measurement
Monitoring system

Intervention groups

1

Description
The experiment group: Acupressure will be performed in this group. The intervention is performed 20 minutes before weaning of mechanically ventilation by a trained person. This technique will be implemented at 5-acupoints on both sides of the body. The 5- acupoints include Zhongfu (Lu1), Taiyuan (Lu9), Hegu (Li4), Neiguan (Pc6) and Zusanli (St36). This technique will be performed on one side of the body first and then the

other side of the body based on the patient's condition. Anxiety, agitation and physiologic parameters are measured before the intervention, immediately after the intervention, under T-piece and 20 min after T-piece. T–piece device is placed on the tracheal tube and a high level of oxygen is given to the patients. In addition to administering oxygen, the device can produce about 5 cm PEEP water and an increase in PaCo2 by providing an exhale-resistant resistor.

Category

Treatment - Other

2

Description

In control group, touch will be performed at 5 points except the main points in intervention group, 20 minutes before weaning of mechanical ventilation. Anxiety, agitation, and physiologic parameters will be measured before the intervention, immediately after the intervention, under T-piece and 20 min after T-piece.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-Ali Sina hospital

Full name of responsible person

Fatemeh Zavareh Esfahani

Street address

No.11, Bu-Ali Sina hospital, Sina Ave, Qazvin.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahed University

Full name of responsible person

Dr. Zahra Kiasalari

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Email

Kiasalari@shahed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shahed University

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

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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