Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of acupressure on anxiety and respiratory parameters in ventilated patients

Protocol summary

Summary

The aim of this study is to assess the effect of acupressure on status of anxiety and respiratory in mechanically ventilated intensive care unit patients admitted in selected hospitals of Medical Science University in Tehran city. Inclusion criteria include GCS ≥ 9; patient intubated from past 24 hours; are on ventilation with SIMV ،PSV ،CPAP or BIPAP mode; have no neuromuscular illness and active heart disease; are not taking any neuromuscular blocker agent and are not taking sedative during past 4 hours. Exclusion criteria is weaning from ventilator during the study. In this randomized clinical trial, 90 patients are randomly placed in two groups, experimental and control, and patients will be blinded .Deep pressure in the experimental group and touch in the control group will perform at the 5- acupoints on both sides of the body .The intervention is performed two times per day over the two days and Each session of intervention will be lasted 20 minutes .Also it is performed at certain times of day for each patient by a trained 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 first and then the other side of the body, based on the patient's condition. Anxiety is measured by Faces anxiety scale and also the effects of anxiety on vital signs (blood pressure, mean blood pressure, heart rate, and respiratory rate and Oxygen saturation of arterial blood). Anxiety and vital signs will be measured baseline, before, immediately after and 2 hours after the intervention in the morning and evening for two days and then one day after the last intervention . The respiratory parameters (respiratory rate, tidal volume, peak inspiratory pressure, minute ventilation, dynamic compliance lung, airway resistance and rapid shallow breathing index) will be measured as a baseline, before, immediately after intervention, 15 minutes, every 30 minutes to 2 hours after the intervention in the morning and evening for two days and then one day after the last intervention. Blood gases at baseline and 2 times per day during the intervention and follow-up will be determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040617140N1**
Registration date: **2014-07-02, 1393/04/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-07-02, 1393/04/11

Registrant information

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Nasim Mehranfard
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Recruitment status

Recruitment complete

Funding source

School of Nursing and Midwifery, Tehran University of Medical Sciences

Expected recruitment start date

2014-09-11, 1393/06/20

Expected recruitment end date

2015-07-11, 1394/04/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of acupressure on anxiety and respiratory parameters in ventilated patients

Public title
Effect of acupressure on anxiety and respiratory parameters in ventilated patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria : GCS ≥ 9 ; Patient intubated for past 24 hours; Are on ventilation with SIMV ،PSV ،CPAP or BIPAP mode; Hemoglobin ≥ 8 mg/dl ; Without malformation or grazes in pressure points ; Have no psychiatric illness ; Have no neuromuscular illness ; Have no active heart disease ; Have no neurologic disorder that affect on respiratory ; Are not taking any psychiatric agent ; Are not taking any neuromuscular blocker agent ; Are not taking sedative during past 4 hours Exclusion criteria :Patient with no cooperation to end of study ; Weaning of mechanical ventilation ; Death of patient during the study ; Discharge from hospital
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Sampling is purposive, then patients will be assigned randomly to experimental and control groups, via a coin toss .

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Sixth Floor, Central Organization of University, Qods St, Keshavarz Blvd
City
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Postal code
1419733171
Approval date
2014-05-25, 1393/03/04
Ethics committee reference number
489/130/93/د

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
Respiratory parameter include expiratory tidal volume
Timepoint
Baseline , before, immediately after intervention, 15 minutes, every 30 minutes to 2 hours after the intervention in the morning and evening for two days and then one day after the last intervention
Method of measurement
Ventilator system

2

Description
Anxiety
Timepoint
Baseline , before, immediately after intervention and 2 hours after intervention in the morning and evening for two days and then one day after the last intervention .
Method of measurement
Faces anxiety scale

Secondary outcomes

1

Description
Blood gases include Arterial blood O2 (Pao2)
Timepoint
Baseline and 2 times per day during the intervention and

follow-up

Method of measurement

ABG system

2

Description

Arterial blood CO2

Timepoint

Baseline and 2 times per day during the intervention and follow-up

Method of measurement

ABG system

3

Description

Arterial blood HCO3-

Timepoint

Baseline and 2 times per day during the intervention and follow-up

Method of measurement

ABG system

4

Description

Blood PH

Timepoint

Baseline and 2 times per day during the intervention and follow-up

Method of measurement

ABG system

5

Description

Respiratory parameters include Dynamic compliance

Timepoint

Baseline , before, immediately after intervention, 15 minutes, every 30 minutes to 2 hours after the intervention in the morning and evening for two days and then one day after the last intervention

Method of measurement

Ventilator system

6

Description

Resistance

Timepoint

Baseline , before, immediately after intervention, 15 minutes, every 30 minutes to 2 hours after the intervention in the morning and evening for two days and then one day after the last intervention

Method of measurement

Ventilator system

7

Description

Oxygen saturation of arterial blood (SPo2)

Timepoint

Baseline , before, immediately after intervention and 2 hours after intervention in the morning and evening for two days and then one day after the last intervention .

Method of measurement

Pulsoximeter

8

Description

Rapid shallow breathing index

Timepoint

Baseline , before, immediately after intervention, 15 minutes, every 30 minutes to 2 hours after the intervention in the morning and evening for two days and then one day after the last intervention

Method of measurement

Ventilator system

9

Description

Respiratory rate

Timepoint

Baseline , before, immediately after intervention, 15 minutes, every 30 minutes to 2 hours after the intervention in the morning and evening for two days and then one day after the last intervention

Method of measurement

Ventilator system

10

Description

Minute ventilation

Timepoint

Baseline , before, immediately after intervention, 15 minutes, every 30 minutes to 2 hours after the intervention in the morning and evening for two days and then one day after the last intervention

Method of measurement

Ventilator system

11

Description

Peak inspiratory pressure

Timepoint

Baseline , before, immediately after intervention, 15 minutes, every 30 minutes to 2 hours after the intervention in the morning and evening for two days and then one day after the last intervention

Method of measurement

Ventilator system

12

Description

Vital signs affected by anxiety include blood pressure

Timepoint

Baseline , before, immediately after intervention and 2 hours after intervention in the morning and evening for two days and then one day after the last intervention

Method of measurement

Monitoring system

13

Description
Heart rate
Timepoint
Baseline , before, immediately after intervention and 2 hours after intervention in the morning and evening for two days and then one day after the last intervention
Method of measurement
Monitoring system

14

Description
Mean blood pressure
Timepoint
Baseline , before, immediately after intervention and 2 hours after intervention in the morning and evening for two days and then one day after the last intervention
Method of measurement
Monitoring system

Intervention groups

1

Description
Acupressure will perform in the experimental group. The intervention is performed two times per day over the two days and each session of intervention will be lasted 20 minutes .Also it is performed at certain times of day for each patient by a trained person. This technique will implement at the 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 is performed on one side of the body first and then the other side of the body, based on the patient's condition.
Category
Treatment - Other

2

Description
In control group, touch will perform at 5 acupoints in 2 sessions per day (morning and evening) during 2 days of intervention period.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Education & Medical Centers of Medical Sceince University in Tehran City
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Tehran University of Medical Sciences
Full name of responsible person
Mr Madadi
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Tehran
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 of Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty