

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 $\geq$ 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

Name

Nasim Mehranfard

Name of organization / entity

School of Nursing and Midwifery of Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

n-mehranfard@razi.tums.ac.ir

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 acupuncture on anxiety and respiratory parameters in ventilated patients

Public title

Effect of acupuncture on anxiety and respiratory parameters in ventilated patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : GCS $\geq$ 9 ; Patient intubated for past 24 hours; Are on ventilation with SIMV ,PSV ,CPAP or BIPAP mode; Hemoglobin $\geq$ 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

AgeFrom **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

Tehran

Postal code

1419733171

Approval date

2014-05-25, 1393/03/04

Ethics committee reference number

489/130/93/3

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 Science University in Tehran City

Full name of responsible person

Nasim Mehranfard

Street address

School of Nursing and Midwifery, Dr Mirkhani St, Tohid Sq

City

Tehran

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

Street address

Central Organization of Tehran University of Medical Sciences ,Keshavarz Blvd

City

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

Contact

Name of organization / entity

School of Nursing and Midwifery of Tehran University of Medical Sciences

Full name of responsible person

Nasim Mehranfard

Position

M.s of Critical Care Nursing

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Dr Mirkhani St, Tohid Sq

City

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Fax

Email
nsmmehranfard@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
School of Nursing and Midwifery of Iran University of Medical Sciences

Full name of responsible person
Jaleh Mohammadaliha

Position
Instructor (mentor)

Other areas of specialty/work

Street address
School of Nursing and Midwifery, Rashid Yasemi St, Valiasr St, Tehran , Iran.

City
Tehran

Postal code

Phone
+98 21 8888 2885

Fax

Email
mohammadaliha.j@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
School of Nursing and Midwifery of Tehran University of Medical Sciences

Full name of responsible person
Nasim Mehranfard

Position
M.s of Critical Care Nursing

Other areas of specialty/work

Street address
School of Nursing and Midwifery, Dr Mirkhani St, Tohid Sq

City
Tehran

Postal code
1419733171

Phone
+98 21 6692 7171

Fax

Email
nsmmehranfard@gmail.com

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