

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation of the effect of acupressure on pain, restlessness and sedation in ventilator patients

Protocol summary

Study aim

Determining the effect of acupressure on the amount of pain, restlessness and the use of sedatives in patients under mechanical ventilation

Design

In this phase one clinical trial, which is conducted in parallel, 60 patients under mechanical ventilation are divided into two intervention and control groups by block randomization method using R statistical software. It is not possible to blind the groups in this study.

Settings and conduct

This study is carried out in the critical care units of Vali Asr hospital in Arak. All patients who are under mechanical ventilation for any reason are studied. Due to the nature of the intervention, blinding is not possible.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Anesthetized patients hospitalized in the intensive care unit who have been treated with mechanical ventilation (SIMV, PSV, CPAP, BIPAP) for 24 hours before and during the intervention; Age between 65-18 years; Stable hemodynamic status of patients; GCS score of 7 and above. Non-inclusion criteria: Death or transfer of the patient from the intensive care unit; Separation from mechanical ventilation; Decreased level of consciousness to less than 7; Induction of anesthesia and use of drugs with neuromuscular blocking effect.

Intervention groups

Intervention group: acupressure is used for them. For this, a special bracelet is used to put pressure on the Neiguan area (P6) in the lower part of the wrist of both hands. This procedure is performed twice a day for three consecutive days. Control group: Acupressure will not be used for patients in the control group and they will receive only the necessary treatments based on the prescription of the attending physicians.

Main outcome variables

Pain; Restlessness; Sedative drugs consumption amount

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220626055279N1**

Registration date: **2022-07-18, 1401/04/27**

Registration timing: **prospective**

Last update: **2022-07-18, 1401/04/27**

Update count: **0**

Registration date

2022-07-18, 1401/04/27

Registrant information

Name

Akbar Mohseni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3368 4982

Email address

akbar111348@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of acupressure on pain, restlessness and sedation in ventilator patients		Secondary Ids	empty
Public title	The effect of acupressure in patients on a ventilator	Ethics committees	
Purpose	Prevention	1	
Inclusion/Exclusion criteria	Inclusion criteria: Anesthetized patients hospitalized in the intensive care unit who have been treated with mechanical ventilation (SIMV, PSV, CPAP, BIPAP) for 24 hours before and during the intervention. Age of 18-65 years old. Stable hemodynamic status of patients. GCS score 7 and above. Not having a wound or any lesion in the desired area for acupressure. Not having a history of mental illness and not taking psychiatric drugs according to the patient's companion. Absence of cardiovascular diseases Having a prescription for a sedative. Exclusion criteria: Death or transfer of the patient from the intensive care unit. Separation from mechanical ventilation. Decreased level of consciousness to less than 7. Induction of anesthesia and use of drugs with neuromuscular blocking effect. A sudden change in the patient's clinical condition due to cardiopulmonary arrest, severe bleeding and other conditions that require medical interventions or surgery. The interference of the bracelet used to physically restrain the patient with the area used in acupressure.	Ethics committee	
Age	From 18 years old to 65 years old	Name of ethics committee	Research Ethics Committee of Arak University of Medical Sciences
Gender	Both	Street address	Arak University of Medical Sciences, Basij Square, Sardasht
Phase	N/A	City	Arak
Groups that have been masked	No information	Province	Markazi
Sample size	Target sample size: 60	Postal code	3819693345
Randomization (investigator's opinion)	Randomized	Approval date	2022-05-22, 1401/03/01
Randomization description	In this study, patients are placed in the intervention (acupressure) or control (conventional method) groups by block randomization. Blocking is used in order to balance the number of samples allocated to each of the studied groups. The size of all blocks is equal and in this experiment we will have two groups of 4 blocks (including 2 Patient in the intervention group and 2 Patient in the control group).	Ethics committee reference number	IR.ARAKMU.REC.1401.071
Blinding (investigator's opinion)	Not blinded	Health conditions studied	
Blinding description		1	
Placebo	Not used	Description of health condition studied	Patients with reduced level of consciousness in the intensive care unit
Assignment	Parallel	ICD-10 code	
Other design features		ICD-10 code description	
		Primary outcomes	
		1	
		Description	Pain score
		Timepoint	Pain assessment is done during the study (3 days), and twice everyday at 12-13 and 18-19
		Method of measurement	Pain score is measured using Behavioral Pain Scale (BPS).
		2	
		Description	The score of calmness and restlessness
		Timepoint	During the study (3 days), and twice everyday at 12-13 and 18-19.
		Method of measurement	Using the Richmond scale
		3	
		Description	

The amount of used sedatives

Timepoint
End of the study period

Method of measurement
Report the amount of medicine taken for the patient in the patient's file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Acupressure is performed using a special bracelet in the lower wrist area (Nigoan area or P6) of both hands for 5 minutes at the same time. This procedure is performed twice a day for three consecutive days.

Category

Treatment - Other

2

Description

Control group: Control group patients receive only routine treatments.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Akbar Mohseni

Street address

Valiasr Hospital, Valiasr Square, Arak

City

Arak

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Markazi

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3818887568

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+98 86 3224 8046

Email

akbar111348@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Alireza Kamali

Street address

School of Nursing, Payabbar Azam Complex, Basij Square, Sardasht

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Arak

Province

Markazi

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3848176941

Phone

+98 86 3383 8309

Email

akbar111348@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Korosh Rezaei

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing, Payabbar Azam Complex, Basij Square, Sardasht

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Markazi

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Akbar Mohseni

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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No.8 ,Shahamat 1 alley, Amir 2 street, Moshaver town

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Demographic characteristics and pain score.

When the data will become available and for how long

Start the access period 6 months after the publication of the results.

To whom data/document is available

All individuals can access the information.

Under which criteria data/document could be used

Nothing.

From where data/document is obtainable

Korosh Rezaei; k.rezaei@arakmu.ac.ir; Arak University of Medical Sciences; 00989183677622.

What processes are involved for a request to access data/document

Two weeks after the applicant's request.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Akbar Mohseni

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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