

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effects of Transcutaneous Electrical Nerve Stimulation (TENS) in Acupuncture Points (Hegu and Zusanli) on Pain and Agitation Reduction under Ventilator ICU Patients

Protocol summary

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Summary

Objectives: This study aimed to investigate the effect of Percutaneous Electrical Nerve Stimulation (TENS) in Acupuncture Points (Hegu and Zusanli) on pain and agitation in intubated patients under ventilator will be carried out. Design: 50 patients with inclusion criteria (having a tracheal tube, patients with pneumonia, non-smoking) in two groups of case and controls (including active TENS and placebo TENS) using a table of random numbers are divided. Variables the severity of pain and agitation is measured by COPT and Richmond Scale will be assess before and after in two groups and As well as Narcotic and sedation consumption.

Recruitment status

Recruitment complete

Funding source

Vice – Chancellery of Research & Technology Affairs of Kermanshah University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050927819N1**

Registration date: **2017-02-10, 1395/11/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Rasool Kawyan Nejad

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Kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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Email address

Scientific title

The Effects of Transcutaneous Electrical Nerve Stimulation (TENS) in Acupuncture Points (Hegu and Zusanli) on Pain and Agitation Reduction under Ventilator ICU Patients

Public title

The Effects of Transcutaneous Electrical Nerve Stimulation (TENS) on Pain and Agitation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having endotracheal tube; Pneumonia patients requiring mechanical ventilation; aged 30 to 50; Placement of electrodes is healthy skin; Blood pressure > 100Hg; Non-zero score on scale of COPT; Non-zero score on scale of Richmond; No smoking or narcotic; New Admission in ICU; 10) GCS > 7 Exclusion criteria: Conditions prohibiting the use of TENS (such as pacemakers, because of the unknown effects of TENS on electrical conduction system or placing the electrode

directly on open wounds); Obesity (weight more than 100 pounds); Skin infection or severe skin disease in the place of the electrodes; Pregnancy

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Building No. 2, Kermanshah University of Medical Science, Shahid Beheshti Boulevard

City

Kermanshah

Postal code

6715847141

Approval date

2016-12-14, 1395/09/24

Ethics committee reference number

IR.kums.REC.1395.533

Health conditions studied

1

Description of health condition studied

Agitation

ICD-10 code

R45.4

ICD-10 code description

Irritability and anger

2

Description of health condition studied

Pain

ICD-10 code

R52

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

Per 2 hours until two day

Method of measurement

using the scale of Critical-Care Pain Observation Tool(CPOT)

2

Description

Agitation

Timepoint

Per 2 hours until two day

Method of measurement

using the scale of Richmond

Secondary outcomes

1

Description

The amount of Narcotic used

Timepoint

48 hourse

Method of measurement

microgram

2

Description

The amount of sedation used

Timepoint

48 hourse

Method of measurement

miligram

Intervention groups

1

Description

TENS devices active: Case group TENS electrodes are placed on points Hegu and zusunli .Then the TENS is turned on with frequency 1-10 Hz and 20-50 mA to using for 30 minutes three times a day. pain and agitation severity is measured per 2 hours by researchers.

Category

Treatment - Devices

2

Description

TENS device disabled: control group TENS electrodes are placed on points Hego and zosunli . Then the TENS is turned off to using for 30 minutes three times a day. pain and agitation severity is measured per 2 hours by researchers.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Javad Aminisaman

Street address

Emam-Reza Hospital, Bagh-e Abrisham

City

kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice - Chancellery of Research & Technology Affairs of Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Behroz Hamze

Street address

Building No. 2, Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice - Chancellery of Research & Technology Affairs of Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Rasool Kaviannezhad

Position

faculty member

Other areas of specialty/work

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MSc in Critical care nursing

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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