

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The Comparison of Effects of Transcutaneous Electrical Nerve Stimulation and Ointment Emla on Pain Associated with Arterial, Venous Blood Sampling, and Intravascular access in Chronic Obstructive Pulmonary Diseases.

Protocol summary

Summary

The aim of this study is comparing of effects of Transcutaneous Electrical Nerve Stimulation (TENS) and Emla Ointment on pain Associated with Arterial and Venous Blood Sampling, and Intravascular access in patients suffering from chronic obstructive pulmonary disease. Inclusion criteria include: being at the age of 30 to 50 years; full Consciousness; No smoking and narcotic use; Healthy skin area. Exclusion criteria include: Not patient's cooperation; Coagulation and bleeding problem at the sampling site; trying to do the procedure more than 5 times. This randomized clinical trial will be conducted among 240 patients with chronic obstructive pulmonary disease in two intervention and control groups. In the intervention group, the electrodes of the Tens apparatus are placed 2 cm above and 2 cm below the sampling site. In the control group, Emla ointment is applied to the site one hour before sampling. Arterial, intravenous of blood sampling and intravenous catheter placement will be performed at the time of using electrical stimulation device in the patients of the intervention group and one hour after using Emla ointment in the control groups at the desired location (Radial artery, Cephalic vein). The pain will be assessed using VAS immediately after intervention and at minutes 1, 3, and 5.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062627819N5**
Registration date: **2017-08-11, 1396/05/20**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-11, 1396/05/20

Registrant information

Name

Rasool Kawyan Nejad

Name of organization / entity

Kermanshah University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Effects of Transcutaneous Electrical Nerve Stimulation and Ointment Emla on Pain Associated with Arterial, Venous Blood Sampling, and Intravascular access in Chronic Obstructive Pulmonary Diseases.

Public title

The Effects of Transcutaneous Electrical Nerve Stimulation and Ointment Emla on Pain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: No smoking; not using narcotics; being at the age of 30 to 50 years old; Healthy skin area; having the ability to understand the pain score and to answer the questions; absence of other pain reasons; No history of dangerous arrhythmia and pacemaker; No history of diabetes. Exclusion criteria: More than 5 times trying to do the procedure; absence of patient cooperation; Coagulation and bleeding problems at the sampling site.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

The closed envelope will be used for randomization.

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 Sciences, Shahid Beheshti Blvd

City

Kermanshah

Postal code

6715847141

Approval date

2017-05-31, 1396/03/10

Ethics committee reference number

IR.kums.REC.1396.117

Health conditions studied**1****Description of health condition studied**

pain

ICD-10 code

R52

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes**1****Description**

Pain

Timepoint

Immediately and minutes 1,3, and 5

Method of measurement

VAS scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: TENS electrodes will be placed at a height of 2 cm above the bottom of the sampling site (Radial artery, Cephalic vein). TENS frequency of 60 to 100 Hz is set.

Category

Treatment - Devices

2**Description**

Control group: Emla ointment is applied to the site one hour before the procedure at the site of Radial artery and Cephalic vein

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza Hospital

Full name of responsible person

Saeed Mohammadi

Street address

Emam Reza Hospital, Parastar Blvd, Bagh e Abrisham

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, 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 chancellor for research, 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

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Position

faculty member

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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