Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 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

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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
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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
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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

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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