Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of using cathodal, anodal direct current stimulation and intermittent with combined analgesia ointment of lidocaine and prilocaine on pain and comfort levels in arterial, vein blood sampling and intramuscular injection processes

Protocol summary

Study aim
This study aims to investigate the effects direct currents and alternating on the pain level caused by venous-arterial blood sampling and intramuscular injections.

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 is conducted on 200 patients.

Settings and conduct
The statistical population includes patients referred to Imam Reza and Imam Khomeini hospitals, Kermanshah city, diagnosed with respiratory failure and infection, who require arterial, venous blood sampling and intramuscular injection. Patients are randomly divided into 5 groups. The research is conducted in a double-blind manner, so that the researcher recording the data and also the patient do not know the type of intervention and grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria: full consciousness, reading, writing and verbal abilities, no addiction, not taking sedatives and painkillers during 24 hours, not having a pacemaker and implantable cardiac defibrillators, not having a history of diabetes and vascular diseases. Exclusion criteria: patients with more than 5 sampling attempts, non-cooperation of the patient, bleeding from the sampling site.

Intervention groups
Control group; patients receive inactive electrical stimulation and an inactive gelatinous substance. The group receiving anesthetic ointment, 1 gram of anesthetic ointment lidocaine and prilocaine is used. Inactive electrode is also placed. In the direct current group of the anodal and cathodal; the application of anode or cathodal direct current is performed at the same time as the needle tip enters the skin. In the group of alternating electrical current stimulation; High-frequency alternating current is applied at the same time as the needle tip enters the skin of the area until the end of the procedure.

Main outcome variables
The pain level, comfort level, Heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240123060780N1**
Registration date: **2024-01-27, 1402/11/07**
Registration timing: **prospective**

Last update: **2024-01-27, 1402/11/07**
Update count: **0**

Registration date
2024-01-27, 1402/11/07

Registrant information

Name
Rasoul Kavyannejad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-02-09, 1402/11/20

Expected recruitment end date

2025-02-08, 1403/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of using cathodal, anodal direct current stimulation and intermittent with combined analgesia ointment of lidocaine and prilocaine on pain and comfort levels in arterial, vein blood sampling and intramuscular injection processes

Public title

Stimulation of cathodic, anodic, alternating current and EMLA anesthetic ointment on pain level and comfort in painful hospital procedures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Full consciousness, literacy, reading, writing, verbal ability and healthy vision, no addiction, the skin of the study area should be healthy, no peripheral edema in the intervention area, not taking sedatives and anesthetic during the last 24 hours, not having a pacemaker and implantable cardiac device and defibrillators, no history of diabetes and vascular diseases.

Exclusion criteria:

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of samples in this study is done by computer software. A random sequence of letters A, B, C, D (for the intervention groups) and E (for the control group) is made in blocks with a random number of 6 and 8 letters. Then these obtained blocks are placed in sealed envelopes. Before starting the study, one of the researchers opens one of the envelopes and finally the patient is placed in one of the intervention or control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the control group, the connection of the electrode to the skin and the needle head is studied, but the device is in inactive mode. Also, a non-effective gelatinous substance (lubricant gel) (similar to the pharmaceutical form of EMLA anesthesia ointment) is used in the control group. In the group receiving anesthetic ointment, anesthetic ointment is placed on the injection or sampling site, and electrodes without electrical stimulation function are also used. Active electrodes of electrical stimulation are used in different groups of electrostimulation devices, but gelatinous substance without effect (lubricant gel) is also used. Therefore, due to the seemingly identical interventions, patients do not know grouping and the type of stimulation interventions. Also, the co-colleague of the variable registration project does not know the type of grouping.

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

No. 2 Central Building, Kermanshah University of Medical Sciences, Shahid Beheshti Street, Kermanshah, Iran

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Approval date

2024-01-16, 1402/10/26

Ethics committee reference number

IR.KUMS.REC.1402.551

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description
Pain
Timepoint
Immediately and in minutes 1, 3 and 5
Method of measurement
The visual analog scale

Secondary outcomes

1

Description
Comfort level
Timepoint
5 minutes after each procedure
Method of measurement
The visual analog scale

2

Description
Heart rate
Timepoint
Before, immediately and in 1,3,5 minutes
Method of measurement
Using portable pulse oximetry

Intervention groups

1

Description
Intervention group; patients in this group receive anodal direct current stimulation (1-5 mA) at the same time as the needle tip enters the skin. Electrical stimulation is performed by connecting the active electrode to the needle tip. The other electrode is connected to the skin in the area far from the needle entry. tip entry area
Category
Treatment - Devices

2

Description
Control group; Patients in this group receive lidocaine (2.5%) and prilocaine (2.5%) local anesthetic ointment in the area of the needle tip one hour before the procedures.
Category
Treatment - Drugs

3

Description
Intervention group; patients in this group receive cathodal direct current stimulation (1-5 mA) at the same time as the needle tip enters the skin. Electrical stimulation is performed by connecting the active electrode to the needle tip. The other electrode is connected to the skin in the area far from the needle entry.
Category
Treatment - Devices

4

Description
Intervention group; patients in this group receive alternating current stimulation (1-5 mA) with a frequency of 50 Hz at the same time as the needle tip enters the skin. Electrical stimulation is performed by connecting the active electrode to the needle tip. The other electrode is connected to the skin in the area far from the needle entry.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Cyrus Jalili

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Grant name

Grant code / Reference number

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

Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
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Position
Assistant professor

Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available