

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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

Country

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

Rasoul Kavyannejad

Street address

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Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

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

Rasoul Kavyannejad

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Position

Assistant professor

Latest degree

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Other areas of specialty/work

Physiology

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Position

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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