Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of EMLA Cream and lidocaine spray with rhythmic breathing on pain intensity due to arterial-venous needles in hemodialysis patients

Protocol summary

Study aim
Comparison the effect of EMLA Cream and lidocaine spray with rhythmic breathing on pain intensity due to arterial-venous needles in hemodialysis patients.

Design
clinical trial with Two-group self-control, parallel, Single blind, 88 patients ,Randomization with quadruple permutation blocks

Settings and conduct
Two methods of EMLA Cream and lidocaine spray with rhythmic breathing are known methods of pain relief. In this study, a comparison of these two methods on the severity of canolation pain in patients undergoing hemodialysis centers in selected hospitals in Ahvaz is investigating. Patients are randomly assigned to two intervention groups: EMLA Cream and lidocaine spray with rhythmic breathing. In each group for control, the pain intensity of fistula cannulation is evaluated before the intervention. To blind the study, the help of a researcher who does not know the type of intervention is used to assess the pain.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - A history of at least 3 months of hemodialysis through fistula - Age over 18 years -Alert - lack of difficulty in accessing arteries -Lack of neuropathic disorders and peripheral vascular diseases - Not receiving painkillers or narcotics or sedatives at least 6 hours before hemodialysis - lack of severe pain in other places - Minimum literacy - lack of Recognized mental disability - lack of addiction or dependence on painkillers - Lack of treatment with sulfonamide, nitrate and phenobarbital - lack of history of Fauvism Exclusion criteria: - The patient's unwillingness to continue cooperating in the research - Unsuccessful cannulation in the first attempt and repeated insertion of the needle into the skin - Creating a critical situation that threatens the patient's life

Intervention groups
1- EMLA Cream Group 2- Lidocaine spray group with rhythmic breathing

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220512054826N1**
Registration date: **2022-05-23, 1401/03/02**
Registration timing: **prospective**

Last update: **2022-05-23, 1401/03/02**
Update count: **0**

Registration date
2022-05-23, 1401/03/02

Registrant information

Name
Mohammad Gholizadeh

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
2022-06-22, 1401/04/01

Expected recruitment end date
2022-09-16, 1401/06/25

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of EMLA Cream and lidocaine spray with rhythmic breathing on pain intensity due to arterial-venous needles in hemodialysis patients

Public title
Comparison the effect of EMLA Cream and lidocaine spray with rhythmic breathing on pain intensity due to arterial-venous needles in hemodialysis patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
A history of at least 3 months of hemodialysis through fistula Age over 18 years Alert lack of difficulty in accessing arteries lack of neuropathic disorders and peripheral vascular diseases Not receiving painkillers or sedatives at least 6 hours before hemodialysis lack of severe pain in other areas Minimum literacy lack of Recognized mental disability lack of addiction or dependence on painkillers Lack of treat with sulfonamides, nitrates and phenobarbital lack of history of Fauvism
Exclusion criteria:
The patient's unwillingness to continue collaborating in the research Unsuccessful cannulation in the first attempt and repeated insertion of the needle into the skin Creating a critical life-threatening situation
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be done first from all patients in the center who meet the inclusion criteria by the available sampling method. They will then be randomly assigned to one of two groups of EMLA cream and lidocaine spray with rhythmic breathing using quadruple permutation blocks. Random allocation of research units was performed using quadruple permutation blocks. For this purpose, the intervention group with EMLA cream, A and the intervention group with lidocaine spray with rhythmic breathing, B will be considered. The quadruple blocks include the six blocks AABB, ABAB, ABBA, BABA, BBAA and BAAB. Each block will be given a code from 1 to 6. Due to the fact that the total sample size of this study was 88 people, the selection of blocks will be done 22 times by throwing the dice and based on the obtained list, patients will be divided into two study groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the outcome evaluator who measures the severity of pain when a dialysis needle enters a fistula is unaware of the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Gonabad University of Medical Sciences
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Khorasan Razavi - Gonabad, Asian Roadside, Vice Chancellor for Research and Technology Gonabad University of Medical Sciences
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Approval date
2022-04-11, 1401/01/22
Ethics committee reference number
IR.GMU.REC.1401.011

Health conditions studied

1

Description of health condition studied
Severe pain of needle insertion into venous arterial fistula in hemodialysis patients
ICD-10 code
T82.848A
ICD-10 code description
Pain from vascular prosthetic devices, implants and grafts, initial encounter

Primary outcomes

1

Description
pain
Timepoint

Before and after the intervention

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the EMLA Cream group, in the first session, patients are given the necessary explanations related to the research, and at the end of the first hemodialysis session, for the next session, the EMLA Cream is provided to patients with a transparent dressing. Patients are instructed to apply 2 grams of the drug at home at the fistula site at an approximate level of 5cm2 on the fistula surface at home 60 minutes before the visit, and to cover the area with a transparent dressing. In the second session, before canulation, the dressing is removed and after disinfecting the area with a cotton swab dipped in 70% alcohol, to prevent venous contraction caused by EMLA Cream, after 10 minutes, hemodialysis needles are inserted into the arteries of the fistula area.

Category

Prevention

2

Description

Intervention group: In the lidocaine spray group with rhythmic breathing, for rhythmic breathing, rhythmic breathing is taught as follows. Two minutes before inserting the vascular needles, perform rhythmic breathing in such a way that the patient closes his eyes, lies on his back (supine) and performs tail inhalation through the nose by counting numbers from 1 to 3 Then, by re-counting the numbers 1 to 3, he holds his breath and by counting the numbers 1 to 3, he exhales through his mouth. All patients in the intervention group are instructed to focus only on the entry and exit of air during respiration. Patients, focusing their minds on this method of breathing, repeat it two minutes before the needle is inserted and during the time the needle is inserted. And in the same group lidocaine spray; After cleaning the skin of the area, two puffs of lidocaine spray (20 mg) are sprayed by the researcher from a distance of 5 cm on the skin surface where the needle enters. Due to the fact that local anesthesia develops 1-5 minutes after the use of lidocaine spray depending on the desired location, 5 minutes after the use of lidocaine spray while the skin of the arterial needle is after disinfecting the area with a cotton swab dipped in 70% alcohol. Needle By a hemodialysis nurse is inserted into the arteries of the fistula area.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Selected hospitals in Ahvaz

Full name of responsible person

Mohammad Gholizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Gonabad 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
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Full name of responsible person
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available