

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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 canulation 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

Country

Iran (Islamic Republic of)

Phone

+98 61 4285 2197

Email address

mohammadgholizadeh762700@gmail.com

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

Street address

Khorasan Razavi - Gonabad, Asian Roadside, Vice Chancellor for Research and Technology Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

9691699967

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 cannulation, 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

Street address

Golestan, Esfand St. Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61 3311 0000

Fax

Email

aduaum@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Leila Sadegh Moghadam

Street address

Asian Roadside, Vice Chancellor for Research and Technology, Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

9691699967

Phone

+98 51 5722 3513

Email

research@gmu.ac.ir

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

Phone

+98 51 5722 3513

Email

amohammadpur@yahoo.com

Person responsible for general inquiries**Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Mohammad Gholizadeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Asian Roadside, Gonabad University of Medical Sciences, School of Nursing

City

Gonabad

Province

Razavi Khorasan

Postal code

9691699967

Phone

+98 51 5722 3513

Email

Mohammadgholizadeh762700@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Mohammad Gholizadeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 4, Mehr

City

Shoush

Province

Khouzestan

Postal code

64781-34438

Phone

+98 61 4285 2197

Email

Mohammadgholizadeh762700@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

دکتر علی محمد پور

Position

Profesor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Asian Roadside, Gonabad University of Medical Sciences, School of Nursing

City

Gonabad

Province

Razavi Khorasan

Postal code

9691699967

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