Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the effect of EMLA cream, lidocaine spray with and without aromatherapy with lavender on pain during Arterio-Venous Fistula (AVF) cannulation among patients undergoing hemodialysis

Protocol summary

Study aim
Compare the impact of using Emla cream and lidocaine spray, with and without lavender aromatherapy, on the pain experienced during Arterio-Venous Fistula (AVF) cannulation

Design
Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

Settings and conduct
The samples available in two hospitals, Amin and Khurshid, patients who meet the criteria for entering this study are selected until the desired number of samples is obtained. reach.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: • Suffering from the final stage of chronic kidney disease • 18 years old and older • Being under hemodialysis for more than 3 months • Passage of 3 months after fistula creation • Exclusion Criteria: • Refuse to participate in the study • Acute illnesses and hospitalizations during the study period

Intervention groups
In the non-intervention method, the arterial-venous hemodialysis needles are inserted into the fistula area by the ward nurse, after finishing the work and fixing the needles, the pain is measured and the amount of pain felt by the patient during the insertion of the arterial-venous needles a After cannulation, lidocaine spray, spelled cream or aromatherapy with lavender is used for all patients during cannulation, or a combination of aromatherapy and lidocaine spray and a combination of aromatherapy and spelled cream. The duration of each intervention is 3 days, and there is a clean period between interventions. There is a 48-hour cleaning period (patients are treated with hemodialysis three times a week, so there is a 48-hour cleaning period between sessions).

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171212037847N2**
Registration date: **2024-12-22, 1403/10/02**
Registration timing: **retrospective**

Last update: **2024-12-22, 1403/10/02**
Update count: **0**

Registration date
2024-12-22, 1403/10/02

Registrant information

Name
Maryam Sadat Hashemi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-05, 1402/12/15

Expected recruitment end date
2024-05-19, 1403/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of EMLA cream, lidocaine spray with and without aromatherapy with lavender on pain during Arterio-Venous Fistula (AVF) cannulation among patients undergoing hemodialysis

Public title
Comparison of the effect of EMLA cream, lidocaine spray with and without aromatherapy with lavender on pain during Arterio-Venous Fistula (AVF) cannulation among patients undergoing hemodialysis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from the final stage of chronic kidney disease 8 years old and older Being under dialysis for more than 3 months No participation in similar research programs at the same time Being conscious Being able to communicate verbally Passage of 3 months after fistula creation and having an efficient fistula
Exclusion criteria:
History of addiction and smoking Presence of skin and vascular lesions in the involved limb Allergy to lidocaine, prilocaine, or other local anesthetics Allergy to essential oils History of asthma, bronchitis, and chronic respiratory diseases Smell problems Severe pain in other organs
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, the researcher uses the easy sampling method, so that among the available samples, patients who meet the criteria for entering this study are selected so that the samples reach the desired number, and then the samples are divided into two groups. The form of random allocation is done using mini-pie software. After minimization software divides the samples among the groups in such a way that there is a minimum difference between them, thus homogenization of the samples is also done and the confounding variables are under control. The desired variables to enter the software include (age, sex, duration of fistula placement and duration of hemodialysis).
Blinding (investigator's opinion)
Single blinded
Blinding description
In this research, the VAS scale is used as a criterion for measuring the pain level of patients. After being at the patient's bedside, the researcher assistant asked the patients to choose the intensity of their pain and draw a line around the desired number. Also, in the data analysis stage, the type of intervention and the intervention and control groups are not known.
Placebo
Not used
Assignment
Parallel
Other design features
There is no specific case

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezarjarib avenue,Isfahan,Iran.
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Approval date
2024-05-19, 1403/02/30
Ethics committee reference number
IR.MUI.NUREMA.REC.1403.035

Health conditions studied

1

Description of health condition studied
Chronic kidney disease, stage 5
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
pain
Timepoint
In 2 occasions, immediately and half an hour after cannulation for 3 days
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Comfort
Timepoint
immediately and half an hour after cannulation for 3 days
Method of measurement
Hemodialysis Comfort Scale.

Intervention groups

1

Description
Intervention group: Intervention group: First, the patients are asked to express their experienced pain based on the visual analogue pain measurement scale in the first three sessions, immediately and 30 minutes after cannulation of the arteriovenous fistula using a routine method without intervention, and the data collected and recorded. Then, during cannulation, lidocaine spray, spelled cream or aromatherapy with lavender is used for all patients, or a combination of aromatherapy and lidocaine spray and a combination of aromatherapy and spelled cream. The duration of each intervention is 3 days. And there is a 48-hour cleaning period between interventions (patients are treated with hemodialysis three times a week, so there is a 48-hour cleaning period between sessions). It should be noted that the order and sequence of interventions is determined randomly for each patient. In this way, the names of 4 interventions are placed in 4 envelopes and the patients are asked to choose one of the envelopes randomly. choose, the first envelope is the first intervention that is done for the patient, then the patient is asked to choose one of the 3 envelopes, the second envelope that is chosen by the patient is the second intervention that is given to the patient Then the patient is asked to choose one of the remaining 2 envelopes, and thus the third intervention is determined, and the last remainingMethod of Spraying Lidocaine:In the lidocaine spray method, the skin is prepared initially and, then, the researcher sprays two puffs of 2% lidocaine (20 mg) onto the skin from a distance of 5 cm. After a five-minute interval, the skin surface around the fistula is disinfected using cotton pads soaked in 70% alcohol, and specialized hemodialysis needles are inserted into the veins of the fistula area by the nurse .Method of Using Emla Cream:For using Emla cream, two ml of Emla cream, based on the instructions for using the product, is applied 45 to 60 minutes before inserting the needle into the fistula and is fixed with a protective dressing. After 45 minutes, the Emla cream is removed from the skin and after disinfecting the area with cotton pads soaked in 70% alcohol, specialized hemodialysis needles are inserted in the veins of the fistula area by the nurse (9). Two minutes and 30 seconds after inserting the arterial needles, the pain intensity is measured by the nurse using a numerical pain intensity scale. To ensure that the previous intervention does not interfere, the interval between interventions is considered .Method of Using Lavender Aromatherapy:In this method, lavender oil is diluted with distilled water/sweet almond oil in a ratio of 1 to 10 (lavender oil 10% produced by Barij Essense Pharmaceutical Company) and, then, three drops of diluted lavender oil is placed on a piece of cotton and the patient is asked to breathe slowly from a distance of 7 to 10 cm and inhale it for 5 minutesLavender oil is typically stored in dark glass bottles with tightly closed lids and is kept in a cool environment, ensuring that no essential oil properties are lost. To assess the long-term effects of lavender oil inhalation, three hemodialysis sessions are implemented per week, and lavender oil inhalation is performed before each hemodialysis session . envelope is the last intervention that will be performed for the patient.
Category
Treatment - Drugs

2

Description
Control group: In the non-intervention method, the arterial-venous hemodialysis needles are inserted into the fistula area by the nurse and, after finishing the work and fixing the needles, the pain is measured and its level felt by the patient during the insertion of the arterial-venous needles is marked and recorded. The level of pain is measured only the first time the nurse inserts any of the arterial or venous needles. If the needles are not initially placed correctly and the nurse needs to make another attempt by piercing the skin again, the patient's pain level will not be measured.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor and Hazrat-e-Ali Asghar Hospital
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Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

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Grant name
Isfahan University of Medical Sciences

Grant code / Reference number

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

Title of funding source
Isfahan 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
Isfahan University of Medical Sciences

Full name of responsible person
Maryam Sadat Hashemi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Critical care Nursing

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Researcher that work in academic and scientific institutes can access to demographic variable and main outcome such as pain
When the data will become available and for how long
Academic and scientific researcher access to data, 6 months after publication result.
To whom data/document is available
Researcher that work in academic and scientific institutes can access to data.
Under which criteria data/document could be used
you can analyse data with SPSS but you do not access to confidential patient data
From where data/document is obtainable
if you need to access to data,you can call with me or send email for me. Call number:00989134118910 Email: maryamhashemi956@gmail.com
What processes are involved for a request to access data/document
After I receive your request,I send them after 10 -30 days
Comments
No comments