

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the Effect of Rhythmic Respiration and Lidocaine Spray on the Severity of Arteriovenous Fistula Venipuncture Pain in Patients undergoing hemodialysis

Protocol summary

Study aim

Comparison of the Effect of Rhythmic Respiration and Lidocaine Spray on the Severity of Arteriovenous Fistula Venipuncture Pain in Patients undergoing Hemodialysis

Design

Two-group self-control, blinded clinical trial, 54 patients, Randomization with quadruple blocks

Settings and conduct

Two methods of rhythmic breathing and Lidocaine spray are known methods of pain relief. In this study, a comparison of these two methods on the severity of fistula canola pain in patients of Nikan Farda Hemodialysis Center in Mashhad is investigated. Patients are randomly assigned to two groups: rhythmic respiration and Lidocaine spray. 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: Be between 18 and 60 years old. Willing to cooperate and participate in research. Known insensitivity to Lidocaine. Do not have verbal, visual or auditory impairment. Criteria for not entering: Onset of other chronic pain that affects the assessment of pain due to the needle entering the arteries of the fistula. Failure to insert the needle into the arteries of the fistula area in the first attempt and the need to repeat the cannulation.

Intervention groups

In the situation without intervention in both groups, no intervention is performed. In the first intervention group, the effect of rhythmic breathing on the pain intensity of dialysis fistula cannulation is investigated. In the second intervention group, the effect of 10% Lidocaine spray on the severity of dialysis fistula cannulation pain is investigated.

Main outcome variables

Dialysis fistula cannulation pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210626051716N1**

Registration date: **2021-07-29, 1400/05/07**

Registration timing: **prospective**

Last update: **2021-07-29, 1400/05/07**

Update count: **0**

Registration date

2021-07-29, 1400/05/07

Registrant information

Name

Houman Sadeghpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3879 3989

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sadeghpourmh3@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-30, 1400/05/08

Expected recruitment end date

2021-08-06, 1400/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title

Comparison of the Effect of Rhythmic Respiration and Lidocaine Spray on the Severity of Arteriovenous Fistula Venipuncture Pain in Patients undergoing hemodialysis

Public title

Comparison of the Effect of Rhythmic Respiration and Lidocaine Spray on the Severity of Arteriovenous Fistula Venipuncture Pain in Patients undergoing hemodialysis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Be between 18 and 60 years old Willing to cooperate and participate in research At least 3 months have passed since the fistula was implanted Lack of pacemaker Having an active record so that three sessions per week and each session for 4 hours to be treated with Hemodialysis Absence of skin problems, lack of anesthesia, neuropathic disorders and peripheral vascular diseases at the fistula site If you have diabetes, have controlled diabetes (FBS samples in the range of 70 to 150 and BS in the range of 120 to 250) Do not have verbal, visual or auditory impairment Lack of known allergy to Lidocaine Do not have drug addiction and dependence on painkillers Have not received painkillers or sedatives 6 hours before Hemodialysis Do not have pain in other parts of the body

Exclusion criteria:

Do not want to continue collaborating in research Lack of patient awareness at any stage of the research Failure of the needle to enter the arteries of the fistula area in the first attempt and the need to repeat the Cannulation Incidence of Lidocaine sensitivity at any stage of the study Onset of other chronic pain that affects the assessment of pain due to needle insertion into the fistula Failure to refer to the research stages (refer to other medical centers to continue treatment, travel, kidney transplant, death)

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **54**

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 rhythmic respiration and lidocaine spray using quadruple permutation blocks. Random allocation

of research units was performed using quadruple permutation blocks. For this purpose, the intervention group with rhythmic breathing will be considered A and the intervention group with lidocaine spray will be considered B. 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. Given that the total sample size of this study was 54 people, blocks will be selected 14 times using dice and According to the list, patients will be divided into two study groups

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor 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

9691793718

Approval date

2021-06-23, 1400/04/02

Ethics committee reference number

IR.GMU.REC.1400.040

Health conditions studied

1

Description of health condition studied

Severity of Arteriovenous Fistula Venipuncture Pain in Patients undergoing Hemodialysis

ICD-10 code

T82.848A

ICD-10 code description

Pain from vascular prosthetic devices, implants and grafts, initial encounter

Primary outcomes

1

Description

"Pain score in Visual Analogue Scale Questionnaire"

Timepoint

"Evaluation of pain score before the intervention and then three consecutive Hemodialysis sessions in both groups"

Method of measurement

" Visual Analogue Scale Questionnaire "

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:The patient is asked during the Hemodialysis session, perform rhythmic breathing two minutes before inserting the vascular needles as follows. Lie down in a comfortable position, close your eyes and do a deep, long breath through the nose with three numbers. Then hold your breath in the lungs and count to three, then exhale slowly through the mouth with three numbers one. By focusing their minds on this method of breathing, patients repeat it over time as Hemodialysis needles are inserted into the arteries of the fistula.This intervention will be repeated three times in a row Hemodialysis on patients in this group.

Category

Prevention

2

Description

Intervention group: In the Lidocaine spray group, lie down in a comfortable position for two minutes before inserting the patient's vascular needles, after cleaning the skin of the needle entry area, two puffs of 10% Lidocaine spray (20 mg) will be sprayed from a distance of 5 cm on the skin surface where the needle enters. 5 minutes after using Lidocaine spray while disinfecting the skin at the site of arterial needle entry with 70% alcohol, the Hemodialysis needle is inserted into the arteries of the fistula area by the ward nurse.This intervention will be repeated three times in a row Hemodialysis on patients in this group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikan farda Hemodialysis center

Full name of responsible person

Nazemiyan Fatemeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Khosravan sahla

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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

Gonabad University of Medical Sciences

Full name of responsible person

Tahere Baloochi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Full name of responsible person

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Individual demographic information and mean pain score evaluated after each intervention and its comparative results will be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions or people who are also engaged in industry

Under which criteria data/document could be used

Submission of documents will be allowed if the purpose of the request is to upgrade and complete or conduct studies in similar fields.

From where data/document is obtainable

1- Phone number: 09394059487 2- Email: SadeghpourMH3@mums.ac.ir 3- Address: Mashhad, 34

Fakuri Blvd., Nikan Farda Hemodialysis Center, Mr. Ali Dorost

What processes are involved for a request to access data/document

First, call 09394059487, which, after coordination, will be provided via email or in person.

Comments