Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Email address
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
Street address
No. 8, Fakouri 34 Ave., Shahid Fakouri Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
91781413655
Phone
+98 51 3880 0124
Fax
+98 51 3880 0128
Email
dorosta861@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Khosravan sahla
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
09691793718
Phone
+98 51 5722 0578
Fax
+98 51 5722 0578
Email
research@gmu.ac.ir
Web page address
http://res.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

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

Street address
School of Nursing, Gonabad University of Medical Sciences, Asian Roadside, Khorasan Razavi - Gonabad

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Phone
+98 51 5722 3028

Fax
+98 51 5722 3815

Email
tbaloochi@gmail.com

Web page address
http://www.gmu.ac.ir/page-DaneshkadehParastariMamaee/FA/0/form/pId489963

Person responsible for scientific 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

Street address
School of Nursing, Gonabad University of Medical Sciences, Asian Roadside, Khorasan Razavi – Gonabad

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Phone
+98 51 5722 3028

Fax
+98 51 5722 3815

Email
tbaloochi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Houman Sadeghpour

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No.26 , Razavi 42 Ave., Razavi Blvd ., Rezashar Town

City
Mashhad

Province
Razavi Khorasan

Postal code
9177718568

Phone
+98 51 3879 3989

Fax
+98 51 3880 0128

Email
SadeghpourMH3@mums.ac.ir

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