Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effectiveness of vapocoolant spray versus lidocaine spray on pain intensity due to insertion of vascular needles in hemodialysis patients

Protocol summary

Study aim

Comparison the effectiveness of vapocoolant versus lidocaine spray on pain intensity due to insertion of vascular needles in hemodialysis patients

Design

The study is a three period cross over double blind randomized Clinical Trial which carry on 4 patients. Randomization is done via blocking and random numbers table.

Settings and conduct

The first needling is performed without any intervention, the pain score is determined one minute after needling.Each of the samples in the next dialysis randomly receives one of the following interventions: vapocoolant ,10% lidocaine spray and placebo(water) in 2 weeks intervals.Vapocoolant sprayed on the skin at a distance of 20 cm for 3 or 4 seconds, allowing the skin to dry for 10 seconds, then disinfect the skin (uniformly temperature-sensitive and uniform for all patients) and 20 seconds after, vascular access is done.Two puff lidocaine sprays are sprayed at approximately 5 cm, 5 minutes after spraying and after disinfection,vascular access is done by the nurse. Inusing the placebo spray, two puff are sprayed at a distance of 5 cm, 5 minutes after spraying and disinfection, vascular access is done.The outer part sprays is covered with paper.The coworker applied the spray to the skin and one minute after needling, the patient's pain score is determined by the presenter without the knowledge of the type of spray. In all patients, the size of needle is 16. In the total stages in each patient, one nurse will work. Nurse and patient will not be aware of the spray type.

Participants/Inclusion and exclusion criteria

All hemodialysis patients. Entering criteria: arteriovenous fistula.Not entering:cardiac disease,lidocain reaction

Intervention groups

The samples in the next dialysis session randomly receives one of the following interventions:vapocoolant spray, 10% lidocaine spray and placebo spray.

Main outcome variables

Reducing the venous access pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180826040868N1**
Registration date: **2018-09-15, 1397/06/24**
Registration timing: **prospective**

Last update: **2018-09-15, 1397/06/24**
Update count: **0**

Registration date

2018-09-15, 1397/06/24

Registrant information

Name

Sima Sadat Hejazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3229 7157

Email address

s.hejazi@nkums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of vapocoolant spray versus lidocaine spray on pain intensity due to insertion of vascular needles in hemodialysis patients

Public title

Effectiveness of vapocoolant spray versus lidocaine spray on vascular needle pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

GCS 15 Ability to speak and understand Farsi or having Persian language translator Not have pacemaker Not have Known cardiac disease Start hemodialysis at least 3 months ago Not have Known reaction to lidocaine Products Not have damaged skin Not analgesic use in the last 24 hours Not use of the cream or products lidocaine in the past Hemodialysis via arteriovenous fistula Not anti arrhythmic medications use (especially Class 3 for example Amiodarone) Perform dialysis three times a week age more than 18 age less than 80

Exclusion criteria:

Skin reaction or abnormal response in arteriovenous fistula site Absence to perform hemodialysis Failure in vascular access by first try at any of the stages

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients undergoing hemodialysis with inclusion criteria are randomly assigned to three intervention groups. First, ABCs, BACs, ACBs, BCAs, CABs, CBAs, and CABs are considered and from zero to five number are allocated to each block, respectively (A vapocoolant spray group, B lidocaine sprays group, C placebo spray group). Then, from the random number table, the number of random samples according to sample size in each group is selected, after deleting the numbers from 6 to 9, is assigned to each corresponding block number. Then numbered and according to the list, patients are assigned to one of three groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants blinding (patients) and clinical caregiver: To prepare placebo sprays, we will empty the lid of lidocaine spray dish and spill it into it. The outer part of each of the three sprays is covered with paper to have an almost identical appearance. Outcome evaluator blinding: In all cases, the coolaborator applies the spray to the skin of the patients and the question of pain score is performed by the executor without notice of the type of spray used. When applying sprays, the executor is not present at the patient's bedside.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of North Khorasan University of Medical Sciences

Street address

Shahriar Street

City

Bojnurd

Province

North Khorasan

Postal code

74877-94149

Approval date

2018-06-24, 1397/04/03

Ethics committee reference number

IR.NKUMS.REC.1397.035

Health conditions studied

1

Description of health condition studied

Venous access pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Pain score

Timepoint

At the beginning of study, two days after, two weeks after the first intervention, four weeks after the first

intervention and six weeks after the first intervention

Method of measurement

Numerical Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Each of the samples in the next dialysis session (two days later) randomly receives one of the following interventions: a vapocoolant spray, 10% lidocaine spray and a placebo spray. Samples who first received a vapocoolant spray (two days later From the initial needle that was without any intervention), two weeks later, lidocaine sprays and four weeks later receive placebo spray. Patients who first receive lidocaine spray receive a vapocoolant spray two weeks after the lidocaine spray, placebo spray, and four weeks after the lidocaine spray, and patients who received the first placebo, two weeks later, a vapocoolant spray and four weeks Lidocaine spray is then applied to the skin.

Category

Prevention

2

Description

Control group: Since the study design is cross-over, each patient is considered to be a control group and receives a placebo spray.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Ali Hospital of Bojnurd

Full name of responsible person
Sima Sadat Hejazi

Street address
Shahriar Street

City
Bojnurd

Province
North Khorasan

Postal code
74877-94149

Phone
+98 58 3229 7010

Email
s.hejazi@nkums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bojnourd University of Medical Sciences

Full name of responsible person
Seyed Kave Hojjat

Street address
Dolat Blvd

City
Bojnurd

Province
North Khorasan

Postal code
74877-94149

Phone
+98 58 3222 1910

Email
S.Kavehhojjat1@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Bojnourd 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
Bojnourd University of Medical Sciences

Full name of responsible person
Sima Sadat Hejazi

Position
Lecturer

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Shahriar Street

City
Bojnurd

Province
North Khorasan

Postal code
9417696786

Phone

+98 58 3229 7096

Email

s.hejazi@nkums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Sima Sadat Hejazi

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahriar Street

City

Bojnurd

Province

North Khorasan

Postal code

94176-96786

Phone

+98 58 3229 7096

Email

s.hejazi@nkums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Sima Sadat Hejazi

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahriar Street

City

Bojnurd

Province

North Khorasan

Postal code

94176-96786

Phone

+98 58 3229 7096

Email

s.hejazi@nkums.ac.ir

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