Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of lidocaine spray and ice spray on the severity of pain during insertion of vascular needles in hemodialysis patients of the dialysis ward

Protocol summary

Study aim
Comparison of the effect of lidocaine spray and ice spray on pain intensity during vascular needle insertion

Design
This is a single-group, placebo-controlled, randomized, randomized, numbered table, phase 3 clinical trial on 48 patients.

Settings and conduct
Study place: Hemodialysis ward of Sabzevar Vasei Hospital; Type of blindness: single blind (patient and nurse); How to blind: Sprays are covered with a paper cover and separated by marks A, B, C.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 18-65 years; Awareness of time, place and person; Need to hospitalize and establish a dialysis line with peripheral vascular needles; Literacy for reading and writing; Possibility of placing vascular needles; No opioid addiction or strong analgesics; Lack of sensitivity to anesthetics; Not having diabetes more than 10 years. Non-inclusion criteria: History of heart disease; Symptoms of decreased sensation and movement in the upper limb under catheterization; Disease-related pain; Consumption of painkillers or drugs

Intervention groups
Intervention 1:Lidocaine spray. After spraying on the spot, the injection is done; Intervention 2: Ice spray. Spray and then inject; Controls: alcohol spray. Spray and then inject. Individuals are immediately asked to rate their pain intensity on the VAS Numerical Pain Scale.

Main outcome variables
Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201017049054N1**
Registration date: **2020-12-27, 1399/10/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-27, 1399/10/07**
Update count: **0**

Registration date
2020-12-27, 1399/10/07

Registrant information

Name
Hamid Roudsarabi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-09, 1399/09/19

Expected recruitment end date
2021-01-08, 1399/10/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of lidocaine spray and ice spray on the severity of pain during insertion of vascular needles in hemodialysis patients of the dialysis ward

Public title
The effect of lidocaine spray and ice spray on reducing injection pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The patient is 18-65 years old. The patient needs to be hospitalized and undergo dialysis with peripheral vascular needles. The patient is aware of the time, place and person. It is possible to place vascular needles for the patient. Literacy for reading and writing. No problems in terms of verbal, mental and visual abilities. No opioid addiction or strong analgesics. Lack of sensitivity to anesthetics. No diabetes for more than 10 years.
Exclusion criteria:
The patient has a history of heart disease. The patient has skin and vascular disorders (erythema, itching, bruising, etc.) at the site of needle entry. The patient has symptoms of decreased sensation and movement in the upper limbs under catheterization. The patient has disease-related pain. The patient should take painkillers or narcotics before the venipuncture and be within the duration of the effect of these drugs.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **48**
More than 1 sample in each individual
Number of samples in each individual: **3**
Each patient receives both an alcohol spray, a lidocaine spray, and an ice spray in different sessions.
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals were selected by simple random sampling using a random number table until all the interventions were identified and finally placed in a group of 48 people. Each person has their own intervention and control. In order to determine which intervention or control each person will be placed in for the first time and the next time, a random number table is used. (For example, from above), then the numbers 0 to 24 are considered for intervention A, the numbers 25 to 49 are considered for intervention B and the numbers 50 to 74 are considered for intervention C. Then we touch one of the numbers and move in one of the predetermined directions and record the numbers and assign them to different interventions.
Blinding (investigator's opinion)
Single blinded
Blinding description
The sprays are covered with a cover whose information is not disclosed and are separated by marks A, B and C. Also, in this case, the researcher himself does not make any intervention that causes the percentage of research error to decrease and is merely an observer of the work. The sprays are given to him. The patient and clinical caregiver are unaware of the contents of the spray used.
Placebo
Used
Assignment
Crossover
Other design features
Ice spray is a sports spray that is used temporarily during level one injuries (scratches, bruises, blows, strains and pressure) that has the property of cooling and temporarily reducing pain temporarily. Easy to use Availability, cheapness and quick effect and getting an effective result in case of sports accidents can be generalized to its use in the clinic.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Sabzevar University of Medical Sciences
Street address
Shohadaye Hasteyi Blvd, Sabzevar.
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Sabzevar
Province
Razavi Khorasan
Postal code
9618738144
Approval date
2020-12-01, 1399/09/11
Ethics committee reference number
IR.MEDSAB.REC.1399.123

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
Z99.2
ICD-10 code description
Dependence on renal dialysis

Primary outcomes

1

Description
Pain score
Timepoint

For each person, the pain is measured immediately after each spray, and at the end of the study, each person determines their pain a total of three times (once for each spray).

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: 10% lidocaine spray (10% lidocaine local anesthetic spray Sina drug) is sprayed in two puffs (20 mg) from a distance of 20 cm on the desired location.

Category

Other

2

Description

Intervention 2: Ice spray (Power Ice Delta Zex Company - Delta Drug Company) is sprayed in the amount of two puffs (2 cc) from a distance of 20 cm on the desired location.

Category

Other

3

Description

Control: Alcohol spray (70% ethanol - Kimia Zanjan Alcoholic Company) is sprayed in the amount of two puffs (140 mg) from a distance of 20 cm on the desired location.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Vasei hospital

Full name of responsible person
Mousareza Tadayonfar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

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

No

Title of funding source

by my own. Hamid Roudsarabi

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Hamid Roudsarabi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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
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