Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Local skin cooling to reduce pain associated with local buffered lidocaine infiltration

Protocol summary

Study aim
Determination of the proper method for creating an appropriate local anesthetic to reduce the pain associated with lidocaine injection.

Design
Double-blind, randomized parallel-group clinical trial

Settings and conduct
After obtaining the code of ethics from the ethics committee of Isfahan University of Medical Sciences and obtaining written consent from 108 eligible patients, they are divided into two groups. In the first group ice cube and in the second group placebo are applied. In the intervention group, an ice cube measuring 2 × 2 × 2 cm (at 0 ° C) in sterile gloves are placed on the wound for 2 minutes, and then buffered lidocaine injection is performed. Immediately after injection, each patient was evaluated to rate the pain using the visual analogue scale (VAS) from 0 to 10.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All alert adult patients admitted to the emergency department of Al-Zahra and Kashani hospitals and requiring lidocaine injection. Exclusion criteria: The presence of visual, mental, and verbal disorders; History of peripheral neuropathy; Allergic reaction to local anesthetics; Those who are in a life-threatening condition.

Intervention groups
In the case group, local ice cubes with zero temperature are used to reduce the pain caused by lidocaine injection, and in the control group, no action is taken before lidocaine injection.

Main outcome variables
The severity of pain is measured based on the VAS scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180129038549N14**
Registration date: **2021-12-15, 1400/09/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-15, 1400/09/24**
Update count: **0**

Registration date
2021-12-15, 1400/09/24

Registrant information

Name
Farhad Heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3786 8804

Email address
drfarhadheydari@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-06, 1400/09/15

Expected recruitment end date
2022-04-19, 1401/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Local skin cooling to reduce pain associated with local buffered lidocaine infiltration

Public title
Effect of local cooling in pain reduction

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients referred to the emergency department Willing to participate in the study Superficial wound/laceration of arm/forearm, ≤5 cm2 Alert
Exclusion criteria:
Visual, mental, or verbal disorders Multiple trauma Unstable vital sign A history of peripheral neuropathy A history of an allergic reaction to local anesthetics
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
After the arrival of the patients to the emergency department, they are divided into 2 groups by a computer-generated random number table with 4 blocks. The selected subjects will be divided into each study group in a randomized block method using 6 rows of four blocks (ABAB-BABA-ABBA-BAAB-AABB-BBAA). Ice cube group (A) and control group (B). Then, from the created blocks, enough blocks are randomly selected to reach the required sample size. Select the number of blocks from the table of random numbers and based on these numbers, the sequence of blocks in each group will be determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
A trained operating room technician performs local cooling in the case group. The wounds of patients in both groups are repaired by the doctor's colleagues and then all the information is collected by a researcher who was blinded to randomization.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Science
Street address
Isfahan University of Medical Science, Hezarjrib Street, Isfahan City
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2019-06-02, 1398/03/12
Ethics committee reference number
IR.MUI.MED.REC.1398.278

Health conditions studied

1

Description of health condition studied
Lidocaine injection pain
ICD-10 code
G89.1
ICD-10 code description
Acute pain, not elsewhere classified

Primary outcomes

1

Description
The severity of pain
Timepoint
After lidocaine injecton
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Drug side effects such as redness, whitening and skin blemishes
Timepoint
Until the time of discharge
Method of measurement
Standard questionnaire form

Intervention groups

1

Description
Intervention group: In the intervention group, an ice cube measuring 2 × 2 × 2 cm (at 0 ° C) in sterile gloves is placed on the wound for 2 minutes, and then buffered

lidocaine injection is performed. Immediately after injection, each patient is evaluated to rate the pain using the visual analogue scale (VAS) from 0 to 10.

Category

Treatment - Drugs

2

Description

Control group: In the control group, no ice cube is used before injecting buffered lidocaine.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital
Full name of responsible person
Farhad Heydari
Street address
Alzahra Hospital, Sofeh Ave., Shahid Keshvari Blvd
City
Isfahan
Province
Isfehan
Postal code
8177777645
Phone
+98 31 3620 2020
Email
drfarhadheydari@gmail.com

2

Recruitment center

Name of recruitment center
Kashani hospital
Full name of responsible person
Farhad Heydari
Street address
Kashani Hospital, kashani Street
City
Isfahan
Province
Isfehan
Postal code
8177777645
Phone
+98 31 3233 0091
Email
drfarhadheydari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash Dastjerdi
Street address
Isfahan University of Medical Science, Hezarjrib Street, Isfahan City
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
siavash@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Farhad Heydari
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
No 7, Aria Building, Sohrevardi Ave.
City
Isfahan
Province
Isfehan
Postal code
8177777645
Phone
+98 31 3776 9818
Fax
Email
drfarhadheydari@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Farhad Heydari

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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Email
drfarhadheydari@gmail.com

Person responsible for updating data

Contact

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Esfahan University of Medical Sciences

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All of the data after coding

When the data will become available and for how long
Six month after publication

To whom data/document is available
Everyone

Under which criteria data/document could be used
For seemingly studies data released to the academic chairman

From where data/document is obtainable
Isfahan University of Medical Sciences

What processes are involved for a request to access data/document
Emailing to farhad_heidari@med.mui.ac.ir

Comments