Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

A Comparative Study on the Effect of Lidocaine Spray and Ice Spray on Pain intensity during Intramuscular Injection

Protocol summary

Study aim
Determination of pain intensity during intramuscular injection in lidocaine spray with ice spray and control group

Design
Controlled clinical trial, parallel, double-blind, nonrandomized,

Settings and conduct
This study is a quasi-experimental clinical trial. Sampling will begin after obtaining permission from the Ethics Committee and authorized by the authorities. After presenting the samples to the researcher, the researcher will provide sufficient explanations regarding the purpose of the study, the method of study, the voluntary participation in the study, and the confidentiality of the information, and will then obtain written consent from them to participate in the study. . Ninety patients referred to injections section of 22 Bahman and Hakim Hospitals will be included in this study. Sampling method in this study will be available as sampling and then according to the days of hospitalization, they were divided into lidocaine spray groups (intervention 1), ice spray (intervention 2) and control, respectively, and sampling until the sample size was completed.

Participants/Inclusion and exclusion criteria
Being conscious; No use of analgesic or sedative medications 6 hours before injections; No severe pain elsewhere, Have not pacemaker; Age over 20 years; No skin problems or numbness at the injection site; No psychiatric problems; No cooperation at any stage of the study.

Intervention groups
Group 1: lidocaine spray; Group 2: ice spray; Group 3: control (no use of any topical anesthetic before injection).

Main outcome variables
Pain intensity.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171219037967N3**
Registration date: **2020-06-06, 1399/03/17**
Registration timing: **retrospective**

Last update: **2020-06-06, 1399/03/17**
Update count: **0**

Registration date
2020-06-06, 1399/03/17

Registrant information

Name
Mehdi Jamalinik

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4441 5745

Email address
mhd.niki67@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

A Comparative Study on the Effect of Lidocaine Spray and Ice Spray on Pain intensity during Intramuscular Injection

Public title
The effect of lidocaine spray and ice spray on pain of intramuscular injection
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
conscious patient Do not take painkillers or sedatives 6 hours before injections No severe pain elsewhere No pacemaker Age over 20 years No skin problems or numbness at the injection site No psychiatric problems
Exclusion criteria:
No consent to participate in the study Chronic diseases
Age
From **20 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Neyshabur School of Medical Sciences
Street address
No. 36, Hekmat 2, Hekmat Ave, Block 6, Tohid town, blo
City
Neyshabour
Province
Razavi Khorasan
Postal code
9617973577
Approval date
2020-01-04, 1398/10/14
Ethics committee reference number
IR.NUMS.REC.1398.029

Health conditions studied

1

Description of health condition studied
Pain during injection
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain score on a numerical scale ruler pain
Timepoint
1 minute after injection
Method of measurement
Numerical Pain Ruler Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group (using lidocaine spray); After cleaning the skin with alcohol cotton, two puffs 10% lidocaine spray from Tehran Drug Company (20 mg) will be sprayed by a researcher at a distance of 5 cm from the skin surface. Because of topical anesthesia occurs 1 to 5 minutes after lidocaine spray administration, the injection will be done five minutes after lidocaine spraying.
Category
Rehabilitation

2

Description
Intervention group: In this group (using ice spray), after cleaning the skin with alcohol cotton, two ice spray puffs (with Dispotech brand made in Italy) will be sprayed by the researcher within 5 cm of the skin surface. Because topical anesthesia occurs 1 to 5 minutes after the application of the ice spray depending on the site in question, the injection will be given five minutes after the application of the ice spray.
Category
Rehabilitation

3

Description
Control group: In this group, the injection will be done in the usual way without intervention.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Hakim Hospital
Full name of responsible person
Mohammad Siavoshi
Street address
Imam Reza Square, next to the highway
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2

Recruitment center
Name of recruitment center
22 Bahman Hospital
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Sponsors / Funding sources

1

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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
Neyshabour 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
Neyshabour University of Medical Sciences
Full name of responsible person
Mohammad Siavoshi
Position
Instructor, Faculty Member
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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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Only part of the data and information about the main outcome can be shared.
When the data will become available and for how long
Start of access period 6 months after printing results
To whom data/document is available
The data for researchers working in academic and scientific institutions and individuals who are engaged in the industry are able to get them to take action
Under which criteria data/document could be used
For similar research
From where data/document is obtainable
The author's email address
What processes are involved for a request to access data/document
1 month after requesting documentation
Comments