# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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
**City**
Neyshabour
**Province**
Razavi Khorasan
**Postal code**
9617973577
**Phone**
+98 51 4441 5745
**Email**
mhd.niki67@yahoo.com

**2**

**Recruitment center**
**Name of recruitment center**
22 Bahman Hospital
**Full name of responsible person**
Mohammad Siavoshi
**Street address**
Imam Khomeini Ave.
**City**
Neyshabour
**Province**
Razavi Khorasan
**Postal code**
9617973577
**Phone**
+98 51 4441 5745
**Email**
mhd.niki67@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Neyshabour University of Medical Sciences
**Full name of responsible person**
Mohammad Siavoshi
**Street address**
Janbazan Blvd, Neyshabour University of Medical Sciences
**City**
Neyshabour
**Province**
Razavi Khorasan
**Postal code**
9617973577
**Phone**
+98 51 4441 5745
**Email**
mhd.niki67@yahoo.com
**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
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
Janbazan Blvd, Neyshabour University of Medical Sciences
**City**
Neyshabour
**Province**
Razavi Khorasan
**Postal code**
9617973577
**Phone**
+98 51 4441 5745
**Email**
siavoshi_mohammad@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Neyshabour University of Medical Sciences

**Full name of responsible person**
Mohammad Siavoshi
**Position**
Instructor, Faculty Member
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
Janbazan Blvd, Neyshabour University of Medical Sciences
**City**
Neyshabour
**Province**
Razavi Khorasan
**Postal code**
9617973577
**Phone**
+98 51 4441 5745
**Email**
siavoshi_mohammad@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Sabzevar University of Medical Sciences
**Full name of responsible person**
Mehdi Jamalinik
**Position**
Instructor, Faculty Member
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
No. 36, Hekmat Ave 2.
**City**
Sabzevar
**Province**
Razavi Khorasan
**Postal code**
9617973577
**Phone**
+98 51 4441 5745
**Email**
mhd.niki67@yahoo.com

## 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**