Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Intranasal lidocaine effect for headache relief in patients at emergency department

Protocol summary

Summary

A randomized placebo-controlled clinical trial will be done among patients with acute headache in emergency department. Patients with history of lidocaine allergy, skull base fracture, GCS<15, and patients younger than 14yo and patients who received a medication in recent two hours will be excluded. Patients will be divided in two groups randomly .After checking the patients vital signs and taking the demographic data, patients will rate their pain on a 10-centimeter visual analogue scale(VAS) prior to drug administration and at 1, 5, 15 and 30 minutes after the initial dose. Medication is one puff of 10% lidocaine spray or normal saline spray(placebo) intranasally. Then the data will be analyzed between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010712050N1**
Registration date: **2013-02-13, 1391/11/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-02-13, 1391/11/25

Registrant information

Name

Mohamadali Jafari Nodushan

Name of organization / entity

Shahid Sadoughi University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1828 4313

Email address

malijafari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2012-12-05, 1391/09/15

Expected recruitment end date

2013-04-20, 1392/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intranasal lidocaine effect for headache relief in patients at emergency department

Public title

Intranasal lidocaine effect for headache relief in patients at emergency department

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with headache. Exclusion criteria: 1. History of lidocaine allergy; 2. Skull base fracture; 3. GCS<15; 4. Patients younger than 14yo; 5. Patients who received a medication in recent two hours; 6. Vital Sign instability.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Sadoughi University of Medical Sciences
Street address
Shahid Sadoughi University of Medical Sciences, Shahid Bahonar Squar
City
Yazd
Postal code
Approval date
2012-02-18, 1390/11/29
Ethics committee reference number
P/17/1/148517

Health conditions studied

1

Description of health condition studied
Headache
ICD-10 code
R51
ICD-10 code description
Headache

2

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine

3

Description of health condition studied
headache
ICD-10 code
G44
ICD-10 code description
Other headache syndromes

Primary outcomes

1

Description
Pain
Timepoint
prior to and at 1, 5, 15 and 30 minutes after intervention
Method of measurement
Numeric Pain Intensity Scale

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: one puff of 10% lidocaine spray in each nasal cavity
Category
Treatment - Drugs

2

Description
control group: one puff of normal saline spray in each nasal cavity
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid doctor Rahnamoon hospital
Full name of responsible person
Mohamadali jafari, Emergency medicine specialist
Street address
Shahid doctor Rahnamoon hospital, Farrokhi street
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of research, Shahid Sadoughi University of medical sciences
Full name of responsible person
Dr Hasan Mozaffari

Street address
Deputy of research, Shahid Sadoughi University of medical science, Shahid Bahonar square
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of research, Shahid Sadoughi University of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Sadoughi University of medical sciences
Full name of responsible person
Mohamadali Jafari
Position
Physician/Emergency medicine specialist
Other areas of specialty/work
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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty