Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Effect of intranasal lidocaine to reduce pain in patients with primary headaches

Protocol summary

Summary

This study evaluate intranasal lidocaine efficacy in patients pain relief with primary headache. Subjects are patients with primary headache presenting to ED (emergency department) diagnosed migrane (with or without aura) , cluster or tension by IHS criteria. Patients are devided in two group ,blindly.case group receive nasal lidocaine, other group receive intranasal normal saline as placebo ,and outcome evaluate by rating pain reduction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212289148N2**
Registration date: **2014-10-11, 1393/07/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-10-11, 1393/07/19

Registrant information

Name

Hassan Barzegari

Name of organization / entity

Golestan Hospital

Country

Iran (Islamic Republic of)

Phone

+98 61 1374 3079

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Recruitment status

Recruitment complete

Funding source

Ahwaz Jundi Shapur University Of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intranasal lidocaine to reduce pain in patients with primary headaches

Public title

Effect of intranasal lidocaine in primary headaches pain relief

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:patients presenting to ED (emergency department)by headache ,diagnosed migrane(with or without aura)or cluster or tension headache,defined by IHS criteria. exclusion criteria: patients who have intranasal lidocaine administration,hemoglobin oxygen saturation below 90%,fever,meningismus,pregnant or lactating patients,recent head trauma ,sizing within last 24 hours,analgesic use within last 2 hours

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

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
Research and Technology Department of Ahwaz Jondishapur Univercity Of Medical
Street address
Ahwaz Jondishapur Univercity Of Medical Sciences
City
Ahwaz
Postal code
Approval date
2012-10-20, 1391/07/29
Ethics committee reference number
U-91159

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

Primary outcomes

1

Description
pain
Timepoint
30 minute after treatment
Method of measurement
visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
lidocaine 2% , 1mg , nasally
Category
Treatment - Drugs

2

Description
normal saline 0.9 %, 1cc , nasally
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
golestan hospital of ahwaz
Full name of responsible person
Street address
City
ahwaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahwaz Jondishapur Univercity Of Medical Sciences
Full name of responsible person
Ahwaz Jondishapur Univercity Of Medical Sciences
Street address
Ahwaz Jondishapur Univercity Of Medical Sciences
City
Ahwaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahwaz Jondishapur Univercity 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

Ahwaz Jondishapur Univercity Of Medical Sciences

Full name of responsible person

Dr. Hassan Barzegari

Position

Emergency Medicine Specialist / Assistant Professor

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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