

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 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 Bamonar 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****Street address**

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ali\_jafari\_25@yahoo.com ; malijafari@ssu.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Sadoughi University of medical sciences

**Full name of responsible person**

Ali Mellat

**Position**

Neurologist

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Mohamadali Jafari

**Position**

Emergency Medicine Specialist

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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*