

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of intra nasal lidocaine 10% & lidocaine 5% for headache relief in head trauma patients referring to emergency department

Protocol summary

Study aim

Comparison of intra nasal lidocaine 10% & lidocaine 5% for headache relief in head trauma patients referring to emergency department

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

This randomized double blind randomized clinical trial (RCT), eighty patients with head trauma had a complaints headache, provided that they did not have a Exclusion Criteria , in two groups of 40 A and B. After obtaining informed consent, group A received 5% Lidocaine Intra Nasal Spray and 10% Lidocaine Intra Nasal Spray for headache. Patients' satisfaction and possible side effects were recorded in the checklist for demographic information, vital signs, severity of headache (NRS) before the administration of the drug, and then at 5, 15, 30, and 1 hour after administration of the drug.

Participants/Inclusion and exclusion criteria

inclusion Criteria;Head trauma patients who do not have a Exclusion Criteria;Exclusion Criteria;Patients aged less than 18 years and over 60 years;Reduced level of consciousness;Instability of vital signs; Lidocaine sensitivity;Symptoms of the fracture of the skull base; Pregnancy and lactation; Bleeding and nasal congestion; Cold symptoms or sinusitis;History of seizure;Patients who have received medication within the last two hours during the current headache and are improving.

Intervention groups

Lidocaine 5% nasal spray was applied to group A and 10% nasal lidocaine spray spray was applied to group B.

Main outcome variables

Determine Comparison& the mean of severity of headache types in the lidocaine group of 10%& 5% lidocaine group at 0,5,15, 30,60 minutes after the start: Determining and comparing patients' satisfaction with treatment in the lidocaine group of 5% and 10%

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181103041539N1**

Registration date: **2018-12-23, 1397/10/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-23, 1397/10/02**

Update count: **0**

Registration date

2018-12-23, 1397/10/02

Registrant information

Name

Fatemeh Tabatabaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3833 5990

Email address

f.tabatabaei@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-11, 1397/08/20

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intra nasal lidocaine 10% & lidocaine 5% for headache relief in head trauma patients referring to emergency department

Public title

Comparison of intra nasal lidocaine 10% & lidocaine 5% for headache relief in head trauma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with head trauma who do not have an Exclusion Criteria

Exclusion criteria:**Age**

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The sprays are sealed in two seals with the names A and B, and the mediator, in such a way as not to be aware of the drug type, prescribes a spray A or B according to a randomized table.

Blinding (investigator's opinion)

Double blinded

Blinding description

After reassuring the eligibility of the criteria for entering the study and obtaining the informed consent of the patient before receiving the drug, the vital signs of the drug during the current headache and the severity of headache were recorded by the Numeric pain scale for the headache by the assessor. After examination of the nasal cavity, if the nasal hole is open, 5% or 10% lidocaine sprays are injected into the nasal spray of a puff in each nasal cavity at the maximum depth by the trained nurse. Sprays are already in indistinguishable coverage and are numbered A and B in such a way that the mediator is not aware of the type of drug and are prescribed to the specimens identified by the accident pattern.

Placebo

Not 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

yazd,School of Medicine- Shahid Sadoughi University of Medical Sciences

City

yazd

Province

Yazd

Postal code

8915173149

Approval date

2017-02-15, 1395/11/27

Ethics committee reference number

IR.SSU.MEDICINE.REC.1395.347

Health conditions studied**1****Description of health condition studied**

head trauma

ICD-10 code

R51

ICD-10 code description

Headache

Primary outcomes**1****Description**

Headache score for patients

Timepoint

Headache score for patients with head trauma at 0, 5, 15, 30 and 60 minutes after medication administration

Method of measurement

numeric pain rating scale

Secondary outcomes**1****Description**

Patient Satisfaction

Timepoint

After an hour of medication administration

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: Group A administered 5% lidocaine spray administered intranasal.

Category

Treatment - Drugs

2

Description

Control group: Group B administered 10% lidocaine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahnamoun hospital

Full name of responsible person

Fatemeh Tabatabaei

Street address

Farokhi Ave, Shahid Rahnamoun Hospital

City

Yazd

Province

Yazd

Postal code

8913814396

Phone

+98 35 3626 8111

Fax

+98 35 3312 3005

Email

f.tabatabaei@ssu.ac.ir

2

Recruitment center

Name of recruitment center

Shahid sadoughi hospital

Full name of responsible person

Fatemeh tabatabaei

Street address

Safaeieh, Shahid sadoughi hospital

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3822 4000

Email

f.tabatabaei@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

Shahid Sadoughi Blv

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3724 0171

Email

F.tabatabaei@ssu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Tabatabaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

No 20, Pasdaran Blv, 9 th

City

Yazd

Province

Yazd

Postal code

8916884120

Phone

+98 35 3833 5990

Email

F.tabatabaei@ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Alireza Esmaeeli

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Paramedical University

City

Abarkooh

Province

Yazd

Postal code

8915173149

Phone

+98 35 3822 9264

Email

Alirezaesmaeili1@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Tabatabaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

No.20, Pasdaran Blvd, 9 th

City

Yazd

Province

Yazd

Postal code

8916884120

Phone

+98 35 3833 5990

Email

f.tabatabaei@ssu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available