Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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