

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The comparison of anesthesia caused by lidocaine injection and lidocaine push with Diphenhydramine injection and Diphenhydramine push in the healing of head and face laceration

Protocol summary

Study aim

The Comparison of anesthesia caused by lidocaine injection or lidocaine push with diphenhydramine injection or diphenhydramine push in the healing of head and face laceration.

Design

Only the researcher is aware of the content of syringes which is used. To create anesthesia, 5 cc of 2% lidocaine and an ampoule of 50 ml of Diphenhydramine in 1 cc mixed with 4 cc of distilled water will be used. In order to eliminate the selection bias, patients with a history of specific and chronic diseases such as diabetes and connective tissue, etc., which delay healing, will be excluded from the study.

Settings and conduct

This study is a double-blind interventional study. In the diphenhydramine group, if the patient's pain is not controlled, the patient will be excluded from the study and the treatment will be continued according to the department's protocol. The data consists of age, sex, location, length of laceration, scale of pain with VAS system. The size and the location of the laceration will be equalized in all 4 groups.

Participants/Inclusion and exclusion criteria

Traumatic patients with cerofacial lacerations with GCS=15. Patients who did not give the permission or have allergic reaction to Lidocaine or Diphenhydramine are excluded from study.

Intervention groups

In one group lidocaine is injected in the margin of wound. Diphenhydramine is the other medicine which will be injected in second group. For the third group lidocaine will be pushed around the margin of the wound and for the fourth group pushing process will be done with diphenhydramine. After 5 minutes we will start the suture of wound. Pain scaling will be done by VAS (Visual Analog Scale) system.

Main outcome variables

Pain during anesthesia Pain during suturing

General information

Reason for update

Acronym

ED

IRCT registration information

IRCT registration number: **IRCT20110814007327N9**

Registration date: **2023-10-29, 1402/08/07**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-29, 1402/08/07**

Update count: **0**

Registration date

2023-10-29, 1402/08/07

Registrant information

Name

Samad Shams Vahdati

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1658 1401

Email address

shams@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of anesthesia caused by lidocaine injection and lidocaine push with Diphenhydramine injection and Diphenhydramine push in the healing of head and face laceration

Public title
The comparison of anesthesia caused by lidocaine injection and/or lidocaine push with Diphenhydramine injection and/or Diphenhydramine push in the healing of head and face laceration.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Traumatic patients who are in the age of 18 to 60 years with GCS=15 with head and/or face laceration
Exclusion criteria:
the patients who did not give permission allergy

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
After obtaining informed consent from patients, using Excel randomization software, patients are entered into 4 groups of 50 patients in parallel using a table of random numbers. Medicines and numbered syringes that only the researcher is aware of are used. In one group, lidocaine is injected around the wound. In one group, diphenhydramine is injected around the wound. In the third group, lidocaine is placed in the wound bed and margin, and in the fourth group, diphenhydramine is placed in the wound bed and margin. After five minutes have passed and anesthesia has taken effect, we will apply stitches. Pain intensity will be evaluated based on VAS. Data including age and sex, wound location, wound length and pain intensity will be collected based on VAS.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the patient is unaware of the type and name of the drug, and the person who will analyze the data will also be unaware of which drug and how the drug is administered, but the doctor, researcher, and nurse are aware of the data. and the results will be

informed

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Tabriz University of Medical Sciences
Street address
Golgasht street
City
Tabriz
Province
East Azarbaijan
Postal code
5156834063

Approval date
2023-04-25, 1402/02/05

Ethics committee reference number
IR.TBZMED.REC.1402.061

Health conditions studied

1

Description of health condition studied
head and/or face laceration

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
pain

Timepoint
Before process, during the injection of anesthesia, At the time of stitching

Method of measurement
VAS scaling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Traumatic patients with cerofacial lacerations with GCS=15. Patients who did not give the permission or have allergic reaction to Lidocaine or Diphenhydramin are excluded from study. Among the groups, the patients will be matched in terms of age and sex, so that after obtaining informed consent from the patients, using Excel randomization software, the patients will be entered into 4 groups of 50 people. Community Verified icon In one group Lidocaine is injected in the margin of wound. Dyphenhydramin is the other medicine which will be injected in second group. For the third group Lidocaine will be pushed around the margin of the wound and for the forth group pushing process will be done with Diphenhydramin. After 5 minutes we will start the suture of wound. Pain scaling will be done by VAS system.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

emergency of EmamReza hospital

Full name of responsible person

Samad Shams vahdati

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Samad Shams vahdati

Position

دانشیار طب اورژانس

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Specialist

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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
all data after analysis will be published as an article
When the data will become available and for how long
one year after publication
To whom data/document is available
all researchers
Under which criteria data/document could be used
for metanalysis and systematic review
From where data/document is obtainable
send mail to sshamsv@gmail.com
What processes are involved for a request to access data/document
in a month
Comments