

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of acetaminophen on pain and outcome of close nasal fracture reduction surgery under local anesthesia, compared with placebo

Protocol summary

Study aim

The effect of acetaminophen on pain and outcome of close nasal fracture reduction surgery under local anesthesia, compared with placebo

Design

Controlled randomized clinical trial with a triple blinded with 68 sample size

Settings and conduct

Patients with nasal fracture referring to AmirAlam Hospital's nasal fracture clinic will be done in 2018. The person responsible for the randomization is out of place and is blind to results. The individual who gives the medication to the patients does not know the type of drug. Patients undergo nasal reduction by a person who is blind to the group in which the patients are located.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age over 18 years; Proper patient tracking; Satisfaction of the patient with localized anesthesia Exclusion Criteria: Patient required open reduction; Having uncontrolled cardiovascular disease; Septum fracture; Cartilage fracture; The use of other analgesic in the last 24 hours

Intervention groups

To the intervention group one hour before the start, 500 mg Acetaminophen tablet is given and to the control group a pill with the same shape and color and taste is given. For all patients, the anterior ethmoidal nerve block and infra orbital with a Lidocaine of 2% C are given in two directions, and the cotton-impregnated with diluted Epinephrine (1 in 100,000 units) will be placed inside the Xylocaine in the nasal cavity of the patient.

Main outcome variables

Pain Intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170108031822N2**

Registration date: **2018-08-15, 1397/05/24**

Registration timing: **prospective**

Last update: **2018-08-15, 1397/05/24**

Update count: **0**

Registration date

2018-08-15, 1397/05/24

Registrant information

Name

Kayvan Aghazadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acetaminophen on pain and outcome of close nasal fracture reduction surgery under local anesthesia, compared with placebo

Public title

The effect of acetaminophen on pain and outcome of close nasal fracture reduction surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Proper follow up patient Patient satisfaction to reduction under local anesthesia

Exclusion criteria:

Patient needs to open reduction Having uncontrolled cardiovascular disease Septum fracture Use of other sedative in the last 24 hours

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by 4 block size

Blinding (investigator's opinion)

Triple blinded

Blinding description

In the present study doctor, the patient and the analyst will be Blind. This clinical trials study is a triple blind study. It is responsible for the randomization of the person who is out of place and blind to results. Patients are numbered based on the block. Medications will be encoded and the person who gives the drugs to the patients is not known about the type of drugs. Patients are placed under close nasal reduction by a person who blinded to the group in which the patients are located.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical

Sciences

Street address

Vice chancellor for research, Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd

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Tehran

Province

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Postal code

1417653761

Approval date

2017-08-19, 1396/05/28

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3225

Health conditions studied

1

Description of health condition studied

Nasal bone Fracture

ICD-10 code

S02.2

ICD-10 code description

Fracture of nasal bones

Primary outcomes

1

Description

Pain Intensity

Timepoint

After nasal fracture reduction

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Take 1 tablet of acetaminophen 500 mg one hour before close nasal fracture reduction

Category

Treatment - Drugs

2

Description

Control group: Use of placebo with the same color and shape and taste

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

AmirAlam hospital

Full name of responsible person

Amirhossein Ghabasiah

Street address

North Saadi St, AmirAlam Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Amirhossein Ghabasiah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Latest degree

Specialist

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Person responsible for updating data

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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

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