Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim
The effect of acetaminophen on pain and outcome of close nasal fracture reduction surgery under local anesthesia, compered 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 ethmoeidal 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)

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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,compered with placebo

Public title
The effect of acetaminophen on pain and outcome of close nssal 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
City
Tehran
Province
Tehran
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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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