

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

New technique for correction of old nasal bone deviation during nasal fracture reduction

Protocol summary

Study aim

Determining the effectiveness of new surgical technique for concomitant treatment of nasal fracture and correction of old nasal bone deviation

Design

This study is a phase 3 quasi clinical trial with no independent control group. Nose aesthetic status and breathing will be compared before and after the intervention in patients with a history of old nasal deviation. The sample size is 30 people

Settings and conduct

The place of study ENT ward of Hamadan hospital 2019-2020

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with new nasal bone fractures with old nose bone deviation. Ages 18-50 years for women and 18-60 years for men. Patient satisfaction to correct old nose bone deviation Exclusion criteria: History of CSF leak, seizures, neurosurgery, maxillofacial surgery in the middle and upper thirds of the face, Coagulopathy, head trauma, reduced consciousness, postoperative trauma, cartilage deformity, nasal fracture, sore fractures Has been,

Intervention groups

In this study, patients with nasal fractures with a history of nasal deviation before recent trauma were enrolled. After induction of general anesthesia, first new fracture treated, then the old nasal deviation is then corrected after the nasal bone is broken.

Main outcome variables

Correction of old nasal deviation with new nasal fracture treatment, increased patient satisfaction with nasal aesthetics and improved nasal breathing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N5**

Registration date: **2019-12-07, 1398/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-07, 1398/09/16**

Update count: **0**

Registration date

2019-12-07, 1398/09/16

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0097

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-20, 1397/12/29

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

New technique for correction of old nasal bone deviation during nasal fracture reduction

Public title

correction of old nasal bone deviation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with new nasal bone fractures with old nose bone deviation Ages 18-50 years for women and 18-60 years for men. Patient satisfaction to correct old nose bone deviation
Exclusion criteria:
 history of CSF leak History of seizures History of neurosurgery, maxillofacial surgery in the middle and upper third of the face A history of coagulopathy Post-operative trauma history, cartilage deformity, nasal fracture

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Hamadan University of Medical Science
Street address
 Shahid Fahmideh
City
 Hamadan
Province
 Hamadan
Postal code
 6517838697
Approval date
 2018-06-08, 1397/03/18
Ethics committee reference number
 IR.UMSHA.REC.1397.145

Health conditions studied

1

Description of health condition studied

Nose deviation

ICD-10 code

J34.2

ICD-10 code description

Deviated nasal septum

Primary outcomes

1

Description

Correction of old nasal bone deviation

Timepoint

Before inserting a new fracture, after removing the mesh and casting, three months after surgery

Method of measurement

Take a photo of the nose

Secondary outcomes

1

Description

Improve patient nasal breathing

Timepoint

Before surgery and three months after surgery

Method of measurement

with NOSE questionnaire

2

Description

Patient satisfaction of nose beauty

Timepoint

Before surgery and three months after surgery

Method of measurement

use of ROE questionnaire

Intervention groups

1

Description

Intervention group: In this study, patients with nasal fractures with a history of nasal deviation before recent trauma were enrolled. After induction of general anesthesia and oro-tracheal tube insertion, the nasal dislocation is first surgically located. To correct the old deviation, first place a two-layer 3 x 3 cm vibrile piece on the most prominent lateral part of the dorsum (to prevent skin injury) and the non-dominant thumb parallel to the eyebrow, gently and without pressure on The eye to protect the eye from accidental impact). At this point, the surgeon uses a surgical hammer with a 30 ° recoil to the horizontal line of the face and from 15 to 20 cm from the nose, simply by moving the wrist (while the arm and

elbow are fixed) to strike the vibrating, The most prominent lateral part of the dorsum enters the convex side. The blows can be repeated to break the old fragment. Then according to the conventional method, if the fragment is unstable (convex or concave), a tetracycline impregnated mesh 4 to 6 cm long between the septum and the moving fragment It is placed in the direction of stability. Then the nose is stabilized by casting. After 5 to 7 days the mesh impregnated with tetracycline and casting is removed

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

dr Roholla Abbasi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

MSc in epidemiology/ Community Medicine MS

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Dr Rohollah Abbasi

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Assistant Professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared except for authors names

When the data will become available and for how long

From 2021 onwards it is permissible

To whom data/document is available

Researchers in all fields

Under which criteria data/document could be used

To develop research and science

From where data/document is obtainable

Correspond to the email address of the scientific responsible for the study

What processes are involved for a request to access data/document

Send and receive email

Comments