

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of simple nasal fracture reduction with over reduction outcoms in patients with nasal fractures.

Protocol summary

Study aim

Comparison of the consequences of simple nasal fracture reduction with over reduction in patients with nasal fractures. Determining the level of patients' satisfaction with the appearance of the nose based on the VAS scale in the simple reduction group. Determining the level of patients' satisfaction with the appearance of the nose based on the VAS scale in the Over Reduction reduction group.

Design

Clinical trial with control group with parallel group, double-blind, randomized, on 40 patients. Excel random function was used for randomization.

Settings and conduct

A clinical trial will be performed on patients referred to Besat Hospital in Hamadan. 40 patients who have suffered a nasal fracture in the last 10 days are randomly divided into two groups. In the first group, which includes 20 patients, nasal implantation It is done simply and in the second group, the placement is done by Over reduction method. The photograph is taken before the placement and 3 months after the placement and is analyzed by an evaluator who has been blinded. The VAS questionnaire is completed by patients and the above data are analyzed by SPSS software.

Participants/Inclusion and exclusion criteria

Having a broken nose during the last 7 to 10 days and no edema and swelling of the nose . Age 15 to 50 years.

Intervention groups

Patients are divided into two groups. In the first group, simple nasal reduction is performed and in the second group, over reduction is performed.

Main outcome variables

Nasal congestion/ Appearance /Satisfaction

General information

Reason for update

Acronym

HNFR

IRCT registration information

IRCT registration number: **IRCT20220509054800N1**
Registration date: **2022-05-18, 1401/02/28**
Registration timing: **prospective**

Last update: **2022-05-18, 1401/02/28**

Update count: **0**

Registration date

2022-05-18, 1401/02/28

Registrant information

Name

Sajad Hadian

Name of organization / entity

Hamedan University of medical science

Country

Iran (Islamic Republic of)

Phone

+98 81 3823 7331

Email address

sajad.hadianp@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-02-18, 1401/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of simple nasal fracture reduction with over reduction outcoms in patients with nasal fractures.

Public title

Over reduction in nasal fracture

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a nose fracture during the last 7 to 10 days and no edema and swelling of the nose. Minimum 15 years and maximum 50 years. Absence of edema and swelling of the nose.

Exclusion criteria:

Open nose fracture. Severe nasal fracture. Need septoplasty. Hematoma septum.

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients by simple, individual randomization, Excel statistical software. After registering the details in Excel software, the patients are randomly divided into two groups A and B by this software. Group A is the control group and group B is the case group. Patients are completely randomly divided into two groups by lottery.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the evaluator who compares the outcome between the two groups are kept blind. Patients are randomly divided into two groups after obtaining informed consent and full explanation of the research. The evaluating physician does not know which group the patients belong to.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamedan University of Medical Sciences.

Street address

No.26.East etemadieh Blvd.Hamedan Town

City

Hamedan

Province

Hamadan

Postal code

6515957581

Approval date

2021-05-02, 1400/02/12

Ethics committee reference number

IR.UMSHA.REC.1400.129

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**

Patient satisfaction with the appearance of the nose.

Timepoint

Before implantation of nasal bone fracture and 3 months after implantation of implantation of nasal bone fracture and 3 months after implantation.

Method of measurement

Visual Analogue Scales.

2**Description**

Nasal congestion

Timepoint

Before surgery and 3 months after surgery.

Method of measurement

Nostad questionnaire

3**Description**

Complications of treatment after surgery such as septal hematoma and tears and any complications that occur after surgery.

Timepoint

After operation

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 patients undergoing over reduction reduction surgery. In this method, the broken nasal bone, after returning to its place, moves a little further away from its place, which returns to its original place if it returns.

Category

Treatment - Surgery

2

Description

Control group: 20 patients undergoing simple nasal bone reduction surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Sajad Hadian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Rohallah Abasi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Sajad Hadian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Full name of responsible person

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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

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