

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of simple nasal fracture reduction with over reduction outcomes 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 outcomes 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

#### Street address

No.26.East Etemadieh Blvd.Hamedan Town

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Hamedan

#### Province

Hamadan

#### Postal code

6515955871

#### Phone

+98 81 3823 7331

#### Email

sajad.hadianp@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Rohallah Abasi

#### Street address

No.26.East Etemadieh Blvd.Hamedan Town

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sajad.hadianp@yahoo.com

### 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

### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Sajad Hadian

#### Position

Resident

#### Latest degree

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#### Other areas of specialty/work

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Sajad Hadian

**Position**

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**Latest degree**

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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