

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The comparison of close reduction of nasal bone fracture, the classic methods of valsham with hands reduction in Patients referring to Khatam-al-Anbia Hospital in Zahedan district.

Protocol summary

Summary

The goal of the single center and double blind study is determination of the success of nasal reduction and The comparison of close reduction of nasal bone fracture, the classic methods of valsham with hands reduction in Patients referring to Khatam-al-Anbia Hospital in Zahedan district. 135 patients were chosen randomly and were divided with the method Random blocks. Inclusion criteria: all patients aged 5 to 50 years with nasal fracture that referring to Khatam-al-Anbia Hospital in Zahedan district. Exit criteria: open fracture, fracture with the rupture of the skin and tissue damage, depress fracture, old fracture, septum damage at the same time. after anesthesia with mask in control group, patients undergo a nasal fracture close reduction with the classic method of valsham (with the use of valsham blades) and the Intervention group, patients undergo a nasal fracture reduction with hand (tenar). the intensity and severity of the impact depending on the surgeon's judgment. the Success in nasal reduction under supervision examiner one month after the intervention is the main goal of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017103137119N1**

Registration date: **2017-11-16, 1396/08/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-16, 1396/08/25

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of research and technology of Zahedan university of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of close reduction of nasal bone fracture, the classic methods of valsham with hands reduction in Patients referring to Khatam-al-Anbia Hospital in Zahedan district.

Public title

Reduction of nasal fracture with hands and comparison with reduction valsham

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients aged 5 to 50 years with nasal fracture that referring to Khatam-al-Anbia Hospital in Zahedan district. Exclusion criteria: open fracture; fracture with the rupture of the skin and tissue damage; depress fracture; old fracture; septum damage at the same time.

Age

From **4 years** old to **49 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences.

Street address

zahedan-The docte Hesabi Account-University of Medical Sciences.

City

Zahedan

Postal code

9816743463

Approval date

2016-07-17, 1395/04/27

Ethics committee reference number

IR.ZAUMS.REC.1395.139

Health conditions studied

1

Description of health condition studied

Fracture of nasal bone

ICD-10 code

S02.2

ICD-10 code description

Fracture of nasal bone

Primary outcomes

1

Description

Success in nasal reduction under supervision examiner

Timepoint

one month after the intervention

Method of measurement

assessment by surgeon according to physical examination

Secondary outcomes

1

Description

Success in nasal reduction from the perspective of the patient in two methods

Timepoint

one month after the intervention

Method of measurement

questionnaire

2

Description

required tampons in two methods

Timepoint

after the reduction

Method of measurement

surgeon's observation

3

Description

the amount of bleeding during the reduction in two methods

Timepoint

during the reduction

Method of measurement

surgeon's observation

Intervention groups

1

Description

Intervention group:patients undergo a nasal fracture reduction with hand(tenar).the intensity and severity of the impact depending on the surgeon's judgment

Category

Treatment - Surgery

2

Description

control group::patients undergo a nasal fracture close reduction with the classic method of valsham(with the use of valsham blades)

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam Al Anbia Hospital
Full name of responsible person
Docter Gholamali Dashti
Street address
City
Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University Of Medical Sciences
Full name of responsible person
Ghazaleh Ashrafzadeh
Street address
Deputy Of Research and Technology, Zahedan
University Of Medical Sciences, The Docter Hesabi
Account, Zahedan University Of Medical Sc
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Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

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Zahedan University Of Medical Sciences
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty