

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Comparing clinical findings of rhinoplasty using a novel combination method of osteotome and reciprocal saw with conventional method of osteotomy

Protocol summary

Study aim

Comparing clinical findings of rhinoplasty using a novel combination method of osteotome and reciprocal saw with conventional method of osteotomy

Design

The plan will attempt to compare clinical findings of rhinoplasty using osteotomy and saw surgery in two intervention groups. Patients are randomly divided into two groups. The consequences of pain and ecchymosis and swelling caused by nose bone osteotomy are examined at second and seventh day after surgery.

Settings and conduct

This prospective study will be conducted in patients referred to Apadana Hospital of Ahvaz and Dey Limited Surgery Center of Arak for rhinoplasty in the age range of 14 to 50 years old regardless of gender.

Participants/Inclusion and exclusion criteria

Exclusion criteria are patients with any kind of renal deformity, no anesthesia contraindication (American Society of Anesthesiologists physical status I and II), no serious airway malformation (septal deviation, breathing dysfunction). Inclusion criterion is men and women between the ages of 14 and 50 require surgery for rhinoplasty.

Intervention groups

The study was divided into two groups of intervention including osteotome and raw and control including traditional osteotomy.

Main outcome variables

Pain, ecchymosis, swelling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170316033094N2**

Registration date: **2020-07-29, 1399/05/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-29, 1399/05/08**

Update count: **0**

Registration date

2020-07-29, 1399/05/08

Registrant information

Name

Mehdi Heidarizade

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing clinical findings of rhinoplasty using a novel combination method of osteotome and reciprocal saw with conventional method of osteotomy

Public title

Novel approach in rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with any kind of nasal deformity No anesthesia contraindication (American Society of Anesthesiologists physical status I and II) No serious airway malformation (septal deviation, breathing dysfunction). Men and women between the ages of 14 and 50 require surgery for rhinoplasty

Exclusion criteria:

Pregnant women Taking antidepressant medications Refusal to participate

Age

From **14 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups using the block randomization method with the following sequences: AABB, ABAB, ABBA, BAAB, and BABA. Group A undergoes the conventional method of osteotomy, and group B undergoes combination novel method of osteotomy and saw. Concealment will be carried out using pocket concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient will be blind about the group of intervention. Due to the finding assessment will be performed after surgery and the method applied is not detectable after surgery hence outcome assessor is automatically blinded regarding the group of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Research Ethics Committee of Arak University of Medical Sciences

Street address

Research and Technology Deputy of Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2020-05-31, 1399/03/11

Ethics committee reference number

IR.ARAKMU.REC.1399.085

Health conditions studied**1****Description of health condition studied**

Rhinoplasty

ICD-10 code

J34

ICD-10 code description

Other and unspecified disorders of nose and nasal sinuses

Primary outcomes**1****Description**

Edema

Timepoint

The second and seventh day after surgery

Method of measurement

Grade 1: The upper and lower eyelids do not interfere with the pupil. Grade 2: A brief coverage of the pupils with some inflation in the eyelids. Grade 3: Complete coverage of the pupil with significant swelling in the eyelids. Grade 4: Complete Eye Closure

2**Description**

Pain

Timepoint

First, second and third after surgery

Method of measurement

VAS scale

3**Description**

Ecchymosis

Timepoint

Day two and seven after surgery

Method of measurement

The KARA method is used to assess ecchymosis. In this way, the results are categorized as follows: Grade 1:

Kimos to 3/1 lower or upper eyelid, or both. Grade 2:
Echimoses up to 2/2 lower or upper eyelid or both. Grade
3: Eclipse of the entire lower or upper eyelid, or both

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This method performed using two instruments together for rhinoplasty including chisel osteotome and reciprocal saw. During the surgery the time of breaking the nasal bones using these two instrument is recorded based on second. In addition, the outcome variables including echymosis, pain, edema and patient's satisfaction are measured at two and seven days after day surgery.

Category

Treatment - Surgery

2

Description

Control group:Osteotome

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dey Limited Surgery Center

Full name of responsible person

Mehdi Heidarizade

Street address

In front of the Department of Transfusion Medicine,
Pharmacy upper floor Bu Ali, Street Shahid Shiroodi
(Khoram), Arak, Iran.

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Email

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Web page address

<http://www.deylimitedsurgerycenter.ir/>

2

Recruitment center

Name of recruitment center

Apadana Hospital

Full name of responsible person

Omid Ghasemzadeh

Street address

North Soroosh Street, Ghods Highway, Ahvaz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak 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

Arak University of Medical Sciences

Proportion provided by this source

1

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

Arak University of Medical Sciences

Full name of responsible person

Mehdi Heidarizade

Position

Assistant Professor of OMFS

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Position

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Latest degree

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Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available