Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

External perforating osteotomy in rhinoplasty comparing ultrasonic cut vs traditional osteotome: A preliminary randomized crossover clinical trial

Protocol summary

Study aim

If the complication of using piezoelectric surgery is reduced, it can replace the usual osteotomy.

Design

Randomised, clinical trial double blinded for patients and postoperative care and outcome assessment with parallel group on 26 patients.

Settings and conduct

26 patients in the maxillofacial surgery service of Imam Khomeini Hospital in Ahvaz at the end of rhinoplasty They are randomly inserted into the piezo ostomy group (study group) or the 2 mm osteotomy group (control group). Each side that is ostomy with one method is ostomy with the other with another device. Lateral osteotomy will be performed externally through the skin using the instrument of choice without lifting the periosteum. And below the medial canthus will be given the skin and superficial muscle aponeurotic tissue (SMAS) and periosteum. Using a small Pizzo PZ3 pen head (Piezotome Acteon Group, Mérignac, France), it will be inserted through the incisions to reach the nasal bone.

Participants/Inclusion and exclusion criteria

Patient intrusion criteria: People over 18 years old Patients with broad dorsum Patient extrusion criteria: History of rhinoplasty nose deviation History of respiratory problems Patients with narrow duodenum

Intervention groups

All patients who meet these criteria are randomly assigned to the piezo osteotomy group (study group) or the 2 mm osteotomy group (control group). Then the priority of right or left osteotomy is randomly selected, but in the end the two groups must be the same in terms of the number of initial piezo or osteotomy and right and left. It should be noted that each side that was osteotomy with one method, the other side is osteotomy with another device.

Main outcome variables

Investigating the amount of bleeding, mucosal rupture, ecchymosis, swelling, pain, skin scar and integrity of the nasal bone and the amount of bone spore in using of piezoelectric rhinoplasty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220104053618N1**
Registration date: **2022-09-23, 1401/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-23, 1401/07/01**
Update count: **0**

Registration date

2022-09-23, 1401/07/01

Registrant information

Name

Bahare Yaghoubi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-17, 1401/06/26

Expected recruitment end date

2022-10-17, 1401/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

External perforating osteotomy in rhinoplasty comparing ultrasonic cut vs traditional osteotome: A preliminary randomized crossover clinical trial

Public title

External perforating osteotomy in rhinoplasty with ultrasonic cut

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

age over18 years old patients without any diseases

Exclusion criteria:

history of rhinoplasty deviation respiratory problems narrow dorsum

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in a simple and individual way Before conducting the study on 26 patients, an envelope will be given to the patients, which will be related to the side of osteotomy with piezoelectric (right or left) and in order to be equal, interventions will be performed randomly in 13 cases on the right side and in the other 13 samples. It will be done on the left And the envelope will be randomly given to the patient, and the surgeon will take the envelope from the patient in the operating room and based on that, he will perform the selected side with piezoelectric and the opposite side with a 2 mm osteotome. The piezo osteotomy side will compare the two sides.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are selected and entered into the study without knowing which side was used for which of the two osteotomy methods, and all patients who meet the mentioned criteria are randomly admitted to the piezo osteotomy group (study group) or 2 mm osteotomy (control group). The person in charge of evaluating patients, clinical results and complications of surgery at the end of surgery and in subsequent follow-up is unaware of the grouping process and the type of osteotomy device on both sides.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of medical sciences

Street address

Golestan st. ,Ahvaz , Iran

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Approval date

2022-09-11, 1401/06/20

Ethics committee reference number

IR.AJUMS.REC.1401.252

Health conditions studied

1

Description of health condition studied

nose deformity

ICD-10 code

Q30.9

ICD-10 code description

Congenital malformation of nose, unspecified

Primary outcomes

1

Description

Eyelid ecchymosis

Timepoint

Comparison and examination of ecchymosis on two sides will be done on days 2, 3, 7, 30 after the operation

Method of measurement

Kara and Gökalan classification system for ecchymosis: grade 1: ecchymosis of the medial third of the upper or lower eyelid or both - grade 2: bruising of the medial two thirds of the upper or lower eyelid or both - grade 3: bruising of the entire length of the upper or lower eyelid or both

2

Description

eyelid edema

Timepoint

Comparison and examination of ecchymosis on two sides will be done on days 2, 3, 7, 30 after the operation

Method of measurement

Kara and Gökalang's classification system for swelling: Grade 1: no pupil covering interference by Hagrid's eyelids - 2: little pupil covering by eyelid swelling - Grade 3: complete pupil covering by significant swelling of Hagrid's eyelids 4: complete closure of the eyes

3

Description

Subconjunctival hemorrhage

Timepoint

Comparison and examination of ecchymosis on two sides will be done on days 2, 3, 7, 30 after the operation.

Method of measurement

Classification system for open and Gökalan Subconjunctival hemorrhage: grade 1: presence of Subconjunctival hemorrhage up to 50% of the congeal surface - grade 2: presence of Subconjunctival hemorrhage with 90% of the congeal surface

4

Description

pain

Timepoint

Comparison and examination of ecchymosis on two sides will be done on days 2, 3, 7, 30 after the operation.

Method of measurement

Pain will be evaluated using a visual analog scale (VAS), in this way, the patient will be given a line marked from 0 to 10, and during three days, he will mark his pain level on the right and left side separately. It means that the number 0 indicates no pain and 10 is the highest value.

5

Description

bleeding

Timepoint

During the operation and immediately post operation

Method of measurement

visual

6

Description

scar

Timepoint

Skin scars will be evaluated one month after surgery.

Method of measurement

The two sides will be compared visually

7

Description

Force for the mobilization of nasal bones

Timepoint

During operation

Method of measurement

Comparison of the amount of pressure required to mobilization of the nasal bones on two sides

8

Description

Uniformity of the osteotomized wall

Timepoint

During operation

Method of measurement

Absence of spores on touch

9

Description

mucosal injury

Timepoint

immediate post operation

Method of measurement

examined endoscopically

10

Description

Bruising and edema

Timepoint

Immediate Post operation

Method of measurement

Visually

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lateral osteotomy using Action piezoelectric device made in France on a sample of 26 person under general anesthesia after 7-10 minutes of injection of lidocaine containing adrenaline 1:100,000 randomly on one side with piezoelectric using a small angle pen head Dar PZ3 with washing 100 ml per minute and mode D2 externally through 2 2 mm skin incisions; The first incision will be made in the caudal area and the second incision will be made 8-10 mm more medial than the medial canthus without lifting the periosteum.

Category

Treatment - Surgery

2

Description

In the control side, the 2-mm wide sharp osteotomes was used on a sample of 26 person under general anesthesia after 7-10 minutes of injection of lidocaine containing adrenaline 1:100,000 randomly on the side opposite to the intervention side (for example, if osteotomy with piezo On the right side, the osteotomy will be performed with the traditional method on the left side and this

procedure will be performed randomly on both sides) with a traditional perforating technique.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Department of Maxillofacial Surgery, Imam Khomeini Hospital, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

بهاره یعقوبی

Position

Resident of oral and maxillofacial surgery

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

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Name of organization / entity
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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
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
Yes - There is 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

Title and more details about the data/document
This study will be approved by the university ethics committee and will receive an IRCT code. All patients after obtaining informed consent and explanation of the surgical approach and complications randomly entered into piezo stoma group (study group) or 2 mm osteotomy group (control group). all data and postoperative complications in two groups are compared and all of them will be examined on days 2, 3, 7, and 30 for pain, swelling, ecchymosis , subconjunctival hemorrhage, and skin scars on both sides of the face, as well as the integrity of the osteotomized lateral wall, the presence of residual deformity, and bone spur immediately post operation will be examined by palpation and mucosal tears and damage will be evaluated with an endoscope. All data can be published after analysis.

When the data will become available and for how long
The data access period is about 3 months after the patients' follow-up from December 1401.

To whom data/document is available
The data will be accessible to all researchers working in academic and educational institutions.

Under which criteria data/document could be used
These data can be used to compare rhinoplasty surgery with piezoelectric and the usual method and to use this approach. The analyzes performed on the data will be reported, which can be used for further studies.

From where data/document is obtainable
To receive the data, the researchers can contact with Dr. Kazem Saujblagachi Khiabani (Khiabani_ak@yahoo.com) and the researcher, Dr. Bahare Yaghoobi (Bahar69.yaghoobi@gmail.com).

What processes are involved for a request to access data/document
After receiving the applicant's email, the data will be available to researchers within three days.

Comments