

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of piezosurgery and conventional external osteotomy post rhinoplasty morbidities (ecchymosis, edema, pain)

Protocol summary

Study aim

Comparison of piezosurgery and conventional external osteotomy post rhinoplasty morbidities (ecchymosis, edema, pain) at imam khomeini hospital, 2021_2023

Design

Tow parallel group, double blinded, randomized with fourth block, sample size 60.

Settings and conduct

In this study 60 rhinoplasty clients chosen from patients of ENT clinic at Imam Khomeini hospital in 1400_1401 and after an informed consent we randomized them in 2 group with tow different way of external osteotomy (piezoelectric or conventional osteotomy) and after surgery we compared their post operation morbidities (edema, ecchymosis, pain) by 2 ENT residents who are blinded about the target of the study, by using their post operation photography in day 4,7 after surgery.

Participants/Inclusion and exclusion criteria

Inclusive criteria: Patient consent Patient without any contraindication for rhinoplasty Exclusive criteria: Revision surgery Severe deformities Anticoagulant medication users Past medical history Current smokers

Intervention groups

In this study in a group we do external osteotomy with piezoelectric osteotom and in the other group we do it with conventional 2 millimeter osteotom.

Main outcome variables

post rhinoplasty edema, ecchymosis and pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110514006468N2**

Registration date: **2021-11-21, 1400/08/30**

Registration timing: **prospective**

Last update: **2021-11-21, 1400/08/30**

Update count: **0**

Registration date

2021-11-21, 1400/08/30

Registrant information

Name

Amin Amali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1628

Email address

a_amali@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of piezosurgery and conventional external osteotomy post rhinoplasty morbidities (ecchymosis, edema, pain)

Public title

Comparison of piezosurgery and conventional external osteotomy post rhinoplasty morbidities (ecchymosis, edema, pain) at imam khomeini hospital, 2021_2023

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

patient consent patient without any contraindication for rhinoplasty

Exclusion criteria:

revision surgery severe deformities anticoagulant medication users past medical history current smokers

Age

From **18 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

we use block randomization. we have blocks of four intervention (A) and four of control (B) groups and write them from 1-6 on cards and put them in a pocket, then choose them by chance and make a sequence of cards. We import patients of interventional or control group of our study from these sequences.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patients, (despite informed consent) will not realize their group. In this study post operation assessors will not know the patients group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tehran university of medical science

Street address

Vice chancellery for research and technology of Tehran university of medical science, , Qods Ave, Keshavarz Blv

City

Tehran

Province

Tehran

Postal code

1981613875

Approval date

2021-09-14, 1400/06/23

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.152

Health conditions studied

1

Description of health condition studied

Rhinoplasty post operation morbidities (edema, ecchymosis, pain)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

post rhinoplasty edema

Timepoint

4 and 7 day after surgery

Method of measurement

Kara and Gökalan (Adopted by Yucel)

2

Description

Post rhinoplasty ecchymosis

Timepoint

4 and 7 day after surgery

Method of measurement

Kara and Gökalan (Adopted by Yucel)

3

Description

pain

Timepoint

4 and 7 day after surgery

Method of measurement

10 point pain ruler scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group we will do external osteotomy with piezoelectric device (POEZOTOME M+ (The ultrasonic expert)) of COMEO company with engine speed 36-28 Khz with 90 angled straight blade (RHS5) and after external incisor (max use of each blade: 3 patient). Other parts of surgery is completely same with control group.

Category

Treatment - Surgery

2

Description

Control group: In this group we will do external osteotomy with conventional 2 millimeter straight blade.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Otorhinolaryngology clinic of Imam Khomeini hospital complex

Full name of responsible person

Amin Amali

Street address

Imam Khomeini hospital complex , Bagherkhan Ave, South Chamran highway

City

Tehran

Province

Tehran

Postal code

1981613875

Phone

+98 21 2211 4286

Email

Zohreh.ghasemii92@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeyan

Street address

Qods Ave, Keshavarz Blv,

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 7381 8898

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Amin Amali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Imam Khomeini hospital complex , Bagherkhan Ave, South Chamran highway

City

Tehran

Province

Tehran

Postal code

141765371

Phone

982161190

Email

zohreh.ghasemii92@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Amin Amali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

South Chamran highway, Bagherkhan Blv, Imam Khomeini hospital complex

City

Tehran

Province

Tehran

Postal code

141765371

Phone
00982161190
Email
ZOHREH.GHASEMI92@GMAIL.COM

982161190
Email
ZOHREH.GHASEMI92@GMAIL.COM

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Amin Amali
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
Street address
South Chamran highway, Bagherkhan Ave, Imam
Khomeini hospital complex
City
Tehran
Province
Tehran
Postal code
141765371
Phone

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