

# 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

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##### Province

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141765371

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982161190

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zohreh.ghasemii92@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

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Associate professor

##### 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**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Amin Amali  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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**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