

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Evaluation of success rate of piezosurgery technique in nasal hump reduction and comparison with conventional method: A randomized double blind clinical trial

#### Protocol summary

##### Summary

The aim of the present study is to evaluate piezosurgery technique ability, in dorsal hump reduction during rhinoplasty. This study is randomized, double blind, with control, single center, phase-2 of clinical trial. Blinding is done for patients and the researcher who measures the outcomes. The main inclusion criterion is presence of a dorsal hump in patient who is candidate for primary rhinoplasty. The main exclusion criteria are history of bleeding in patient or his or her family; consumption of drugs which intervene with coagulation system; consumption of oral contraceptive drugs. Target sample size is 20 patients. In intervention group, hump reduction is done with piezosurgery technique. In control group, hump reduction is conducted with conventional method (osteotome and rasp). The time of this intervention is after primary tip plasty. Primary outcomes are symmetry of nasal dorsum, the compatibility rate of the amount of acquired hump reduction after surgery with the predetermined amount (during presurgical phase), the rate of patient's satisfaction about final appearance of nasal dorsum. Secondary outcomes consist of: bony irregularities of nasal dorsum, bony prominence of nasal dorsum, cutaneous complications in nasal dorsum.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201610219926N3**

Registration date: **2017-01-06, 1395/10/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-01-06, 1395/10/17

#### Registrant information

##### Name

Mohammad Reza Jamalpour

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1826 0356

##### Email address

jamalpour@umsha.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice-chancellors of research and Technology, Hamadan University of Medical Sciences

#### Expected recruitment start date

2017-01-07, 1395/10/18

#### Expected recruitment end date

2017-04-22, 1396/02/02

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of success rate of piezosurgery technique in nasal hump reduction and comparison with conventional method: A randomized double blind clinical trial

#### Public title

Using of piezosurgery technique in rhinoplasty for nasal hump reduction

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

The inclusion criteria are presence of dorsal hump in a patient, who is candidate for primary rhinoplasty; ASA (American Society of Anesthesiologists) class I patients. The exclusion criteria are history of bleeding in patient or his or her family; consumption of drugs which intervene with coagulation system; consumption of oral contraceptive drugs; secondary nasal deformity.

#### Age

From **18 years** old to **50 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **20**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Blinding technique: It is stipulated in consent form that after participating of patient in this study, he or she will be treated randomly with one of the surgical techniques (piezosurgery or conventional method). The researcher who would measure the outcomes is a maxillofacial surgeon (other than the surgeon who has done the operations) and he do not know anything about groups. Randomized allocation of samples to intervention and control groups will be done with blocked randomization.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

##### Street address

No.16, Hamadan University of Medical Sciences, Shahid Fahmideh street, Ganjnameh street

##### City

Hamadan

##### Postal code

#### Approval date

2016-09-22, 1395/07/01

#### Ethics committee reference number

IR.UMSHA.REC.1395.250

## Health conditions studied

### 1

#### Description of health condition studied

Nasal deformity

#### ICD-10 code

XVII

#### ICD-10 code description

Q10-Q18 Congenital malformations of eye, ear, face and neck

## Primary outcomes

### 1

#### Description

Symmetry of nasal dorsum

#### Timepoint

Ten days, 4 weeks, 3 months after intervention

#### Method of measurement

Questionnaire

### 2

#### Description

Compatibility rate of the amount of acquired hump reduction after surgery with the predetermined amount (during presurgical phase)

#### Timepoint

Three months after intervention

#### Method of measurement

Questionnaire

### 3

#### Description

Rate of patient's satisfaction about final appearance of nasal dorsum

#### Timepoint

Three months after intervention

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Bony irregularities of nasal dorsum

#### Timepoint

Ten days, 4 weeks, 3 months after intervention

#### Method of measurement

Questionnaire

### 2

#### Description

Bony prominence of nasal dorsum

#### Timepoint

Ten days, 4 weeks, 3 months after intervention

#### Method of measurement

Questionnaire

### 3

#### Description

Cutaneous complications in nasal dorsum

#### Timepoint

Ten days, 4 weeks, 3 months after intervention

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Hump reduction is done with piezosurgery technique.

#### Category

Treatment - Surgery

### 2

#### Description

Hump reduction is conducted with osteotome and rasp.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital

##### Full name of responsible person

Mohammad Reza Jamalpour

##### Street address

No.20, Mazdaghineh street, Shahid Behshti street

##### City

Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellors of Research and Technology,  
Hamadan University of Medical Sciences

##### Full name of responsible person

Maryam Askarinia

##### Street address

No.14, Vice-chancellors of Research and Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh street, Ganjnameh street

##### City

Hamadan

##### Grant name

##### Grant code / Reference number

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

Yes

#### Title of funding source

Vice-chancellors of Research and Technology, Hamadan  
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

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Full name of responsible person

Mohammad Reza Jamalpour

##### Position

Associated Professor of Oral and Maxillofacial Surgery

##### Other areas of specialty/work

##### Street address

No.18, Dental Faculty, Hamadan University of Medical  
Sciences, Shahid Fahmideh street, Ganjnameh street

##### City

Hamadan

##### Postal code

##### Phone

+98 81 3838 1059

##### Fax

##### Email

jamalpour@umsha.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Full name of responsible person

Mohammad Reza Jamalpour

##### Position

Associated professor of Oral and Maxillofacial Surgery

##### Other areas of specialty/work

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**Other areas of specialty/work****Street address**

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jamalpour@umsha.ac.ir

**Web page address**

## 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*