Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 commitee 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 monthes 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 monthes after iontervention

Method of measurement
Questionnaire

3

Description
Rate of patient’s satisfaction about final appearance of nasal dorsum

Timepoint
Three monthes after intervention

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Bony irregularities of nasal dorsum

Timepoint
Ten days, 4 weeks, 3 monthes after intervention

Method of measurement
Questionnaire

2

Description
Bony prominence of nasal dorsum

Timepoint
Ten days, 4 weeks, 3 monthes after intervention

Method of measurement

Questionnaire

3

Description
Cutaneous complications in nasal dorsum
Timepoint
Ten days, 4 weeks, 3 monthes 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
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
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Web page address

Person responsible for updating data

Contact

Name of organization / entity
Hamadan University of Medical Sciences

Full name of responsible person
Mohammad Reza Jamalpour

Position
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Fax

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jamalpour@umsha.ac.ir

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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