

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effects of using Buccal Fat pad on dorsum changes.

Protocol summary

Study aim

The effects of using Buccal Fat pad on dorsum changes

Design

This study is a single blind randomized clinical trial with control group. 20 patients will be randomly divided into two groups of intervention (I) or control (C).

Settings and conduct

This single blind study(The person who measures the outcome will be unaware of the groups) will be performed in Beast hospital of Hamadan to determine the effect of using Buccal Fat pad on dorsum changes In patients undergoing primary rhinoplasty

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient satisfaction to participate in the study, age 18 - 40 years old, Class I according to the American Association of Anesthesiologists (ASA I)
exclusion criteria: History of nose trauma, History of respiratory problems and History of previous rhinoplasty

Intervention groups

In patients undergoing primary rhinoplasty, after removal of nasal bridge bone and before the suture of the nasal skin, with small incision in the oral cavity a small amount of buccal fat is removed and to be laid on the nasal dorsum and will be fixed to this area then skin will be sutured. In the control group, the skin is sutured without use of buccal fat.

Main outcome variables

Nasal bridge beauty change

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120531009926N8**

Registration date: **2020-03-25, 1399/01/06**

Registration timing: **retrospective**

Last update: **2020-03-25, 1399/01/06**

Update count: **0**

Registration date

2020-03-25, 1399/01/06

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

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of using Buccal Fat pad on dorsum changes.

Public title

The effects of using Buccal Fat pad on dorsum changes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient satisfaction to participate in the study age 18 - 40 years old American Society of Anesthesiologists class I (ASA I)

Exclusion criteria:

History of nose trauma History of respiratory problems
History of previous rhinoplasty

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

We made 20 cards and wrote letter I on 10 for intervention and on the other 10, letter C for the control group. Then we put them inside the envelope with aluminum wrap then we'll put it in the box. At the time of patient arrival, one of the envelopes will be randomly selected and opened. based on selected letter (I or C), patients will be assigned to intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the individual who evaluating the outcome of the intervention will be unaware of the intervention and control groups, Therefore, the study will be single blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of medical sciences

Street address

Shahid Fahmideh

City

Hamadan

Province

Hamadan

Postal code

6517838677

Approval date

2018-04-13, 1397/01/24

Ethics committee reference number

IR.UMSHA.REC.1398.006

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Nasal bridge Beauty changes.

Timepoint

Immediately after splint removal and at 2, 4 and 6 months after surgery

Method of measurement

Patients' satisfaction of nasal dorsum with Visual Analogue Scale (VAS) and Facial Outcome Evaluation(FOE)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In intervention group open techniques for Primary Rhinoplasty will be used. with small incision in the maxillary vestibular area, buccal fat pad with tissues attached to it is retained to provide tissue nutrition during surgery and incision site will be sutured. After the end of the osteotomy and before the suture of the nasal skin, a layer of fat tissue removed from the mouth is inserted on the nasal dorsum and fixed.

Category

Treatment - Surgery

2

Description

Control group: In the control group, In this group, primary rhinoplasty surgery will be performed with open technique and after the end of the osteotomy, nasal skin will be immediately sutured without use of buccal fat

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and Maxillofacial Surgery Clinic, Besat Hospital, Hamadan

Full name of responsible person
Dr.Mohammadreza Jamalpour
Street address
Besat Hospital, Shahid Beheshti Blv, Hamedan
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6514845411
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+98 81 3264 0081
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Besat@Umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Vice-chancellor for research and technology, Shahid Fahmideh, Hamadan
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vc_research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person

Dr Mohammadreza Jamalpour

Position

Associate professor of Hamadan Dental School

Latest degree

Specialist

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

Dr Mohammadreza Jamalpour

Position

Associate Professor , Faculty of Dentistry, Hamadan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Professor, Faculty of Dentistry, Hamadan University of Medical Sciences

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Proposal and method of conducting the study can be shared in areas specified by citing the source

When the data will become available and for how long

21/3/219 to 19/3/2020

To whom data/document is available

Oral and Maxillary Surgeons and Researchers

Under which criteria data/document could be used

To improve rhinoplasty surgical treatment

From where data/document is obtainable

Dr.mohammadreza jamalpoor

What processes are involved for a request to access data/document

Email

Comments