

# 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 Best 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  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
6514845411  
**Phone**  
+98 81 3264 0081  
**Email**  
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  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
6517838677  
**Phone**  
+98 81 3264 0081  
**Email**  
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

#### Street address

Shahid Beheshti Ave, Hamadan

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6514845411

#### Phone

+98 81 3264 0081

#### Email

jamalpour1972@gmail.com

## Person responsible for scientific inquiries

#### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

#### 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

Hamedan University of Medical Sciences

#### Full name of responsible person

Dr Mohammadreza Jamalpour

#### Position

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**