

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Evaluation of facial contour changes following buccal fat pad removal surgery

#### Protocol summary

##### Study aim

Evaluation of facial contour changes following buccal fat pad removal surgery

##### Design

A clinical non randomised trial, without controlled group, phase 2 on 15 patients, with postoperative care and outcome assessment

##### Settings and conduct

Location: Tehran Farhikhtegan Hospital Preparation of preoperative images: 3-D scans, 2-D photography in frontal and left and right profile and left and right 45 degree view, Ultrasound from each site of the face Method: injection of local anesthesia Lidocaine 2% in buccal area. Make an incision about 1cm between Parotid duct and buccal vestibula in the vicinity of upper 6 tooth, take out buccal fat pad without any external force, suturing of incision with resorbable suture 3\_0.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Medium body size Normal facial muscles function Normal facial nerve function Among 20 to 50 years old Exclusion criteria: Systemic diseases An history of trauma in the face area An history of surgery in the face area An history of filler or botox injection in the face area Using anticoagulant drugs

##### Intervention groups

Buccal fat pad removal surgery and its effect on facial buccal contour by using 3-D scanner device before and after of operation. There is no control group.

##### Main outcome variables

Facial buccal contour

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230909059385N1**

Registration date: **2023-09-18, 1402/06/27**

Registration timing: **prospective**

Last update: **2023-09-18, 1402/06/27**

Update count: **0**

##### Registration date

2023-09-18, 1402/06/27

##### Registrant information

###### Name

Marjan Hosseinpour

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4482 1976

###### Email address

marjan.hosseinpour6623@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2023-10-07, 1402/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of facial contour changes following buccal fat pad removal surgery

##### Public title

Evaluation of Buccal fat pad removal surgery on facial contour

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Individuals applying buccal fat pad removal surgery  
Medium body size Individuals in between 20-50 years old  
Normal facial muscles function Normal facial nerve function

**Exclusion criteria:**

Lactating and pregnant mothers Patients with acute and chronic diseases History of trauma Taking anticoagulant drugs Masseter muscle hypertrophy Mandibular angle hypertrophy Weight changes during the study

**Age**

From **20 years** old to **50 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **2**

Buccal face contour on each side of the face

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

Using a 3\_D scanning device in order to examin changes in facial contour

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tehran Azad University of Medical Sciences

**Street address**

Tehran Islamic Azad University of Medical Sciences, Khaghani Ave., Shariati Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1916893813

**Approval date**

2023-06-12, 1402/03/22

**Ethics committee reference number**

IR.IAU.DENTAL.REC.1402.049

**Health conditions studied**

1

**Description of health condition studied**

Buccal fat pad

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Facial buccal contour

**Timepoint**

Before operation and 6 monthes after operation

**Method of measurement**

3-D scanner device and questionnaire

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: Buccal fat pad removal surgery

**Category**

Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Farhikhtegan Hospital

**Full name of responsible person**

Marjan hosseinpour

**Street address**

Farhikhtegan Hospital, Sattari Expy

**City**

Tehran

**Province**

Tehran

**Postal code**

1469856333

**Phone**

+98 912 226 9748

**Email**

Marjan.hosseinpour6623@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. Masoud Parsania

**Street address**

Headquarters of Tehran Medical Science of Islamic Azad University, Gole Yakh Ave., Aeine Blvd., Shariati Ave., Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1949635881

**Phone**

+98 21 2264 0599

**Fax**

+98 21 2264 0599

**Email**

iuc@iautmu.ac.ir

**Web page address**

<http://tms.iau.ir/research/fa>

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Marjan Hosseinpour

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**Contact**

**Name of organization / entity**

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**Contact**

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**Latest degree**

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## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

### **Justification/reason for indecision/not sharing IPD**

Because of moral issues

### **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