

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Investigation of the effect of Sulcular incision on the surrounding soft tissue in Lefort I Osteotomy.

#### Protocol summary

##### Study aim

Investigation of the effect of Sulcular incision on Upper Lip height, Nasolabial angle, height of Incisor teeth crown & Alar base widening

##### Design

This study perform using prospective randomized clinical trial. The studing population include patients aged 18 to 31 years (mean age 21.8) who undergo LeFort I maxillary advancement with or without impaction. In these randomly select people, salcular incision made to access the maxillary bone, and soft tissue variations measure and compare before and 12 months after the surgery. According to similar studies in this regard, the number of samples for salcular incision in Lefort I osteotomy set at 20 people. Using Minitab softwarewith 90% test power, the number of patients require for the study was determine.

##### Settings and conduct

This study will be performed on eligible patients in Imam Khomeini Hospital and private hospitals in Ahvaz. In this study, 20 patients who underwent preoperative orthodontic treatment and are ready for Lefort I orthognathic orthognathic surgery will be randomly selected and enrolled in the study. Surgical treatment plan for orthognathic surgery process of these patients will be Lefort I adjuvant osteotomy surgery alone or with maxillary implantation using salcular incision.

##### Participants/Inclusion and exclusion criteria

Patients who candidate for maxillary advancement lefort I osteotomy with or without impaction does enter to this study; Patients with lip & palate cleft, old midface fracture, thin gingiva biotype does not enter to this study.

##### Intervention groups

We have one intervention group in which we will use soft tissue sulcular incision. Before and one year after surgery, the size of the upper lip, the display of the maxilla incisor and the nasolabial angle will be investigated.

#### Main outcome variables

Upper lip height; Nasolabial angle; Alarbase widening; height of incisor teeth crown

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200907048648N1**

Registration date: **2020-09-13, 1399/06/23**

Registration timing: **prospective**

Last update: **2020-09-13, 1399/06/23**

Update count: **0**

##### Registration date

2020-09-13, 1399/06/23

##### Registrant information

##### Name

Marzie Akhtari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 5332 7839

##### Email address

akhtari.m@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2020-10-21, 1399/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Investigation of the effect of Sulcular incision on the surrounding soft tissue in Lefort I Osteotomy.

**Public title**  
Investigation of the effect of Sulcular incision in Lefort I Osteotomy.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients who candidate for Advancement Lefort I Osteotomy with or without Impaction

**Exclusion criteria:**

Patients with Lip & Palate cleft Patients with old Midface fracture patients with thin biotype Gingiva

**Age**

From **18 years** old to **32 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Ahvaz Jundi Shapour University of Medical Sciences

**Street address**

Ahvaz University, Dey Ave., Golestan Blvd.

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Approval date**

2019-08-21, 1398/05/30

**Ethics committee reference number**

IR.AJUMS.REC.1398.305

**Health conditions studied**

**1**

**Description of health condition studied**

investigate for soft tissue changes

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Upper lip length from subnasale to ostomion

**Timepoint**

The variables are measured before surgery and 12 months after surgery.

**Method of measurement**

Caliper marked by GB-19001,mitutoyo,Japan

**2**

**Description**

Nasolabial angle in the area between the columela and upper lip

**Timepoint**

The variables are measured before surgery and 12 months after surgery.

**Method of measurement**

Caliper marked by GB-19001,mitutoyo,Japan

**3**

**Description**

incisor crown length from sulcus

**Timepoint**

The variables are measured before surgery and 12 months after surgery.

**Method of measurement**

Caliper marked by GB-19001,mitutoyo,Japan

**4**

**Description**

Alarbase widening by measuring the distance between the alars

**Timepoint**

The variables are measured before surgery and 12 months after surgery.

**Method of measurement**

Caliper marked by GB-19001,mitutoyo,Japan

**Secondary outcomes**

empty

## Intervention groups

1

### Description

It consists of a group of 20 people who will undergo lefort 1 maxillary advancement osteotomy with or without impaction. In this group, sulcular incision method will be used.

### Category

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Emam Khomeini Hospital

#### Full name of responsible person

shahrokh raeesian

#### Street address

Emam Khomeini Hospital,24 Meters AVE.

#### City

Ahvaz

#### Province

Khouzestan

#### Postal code

6135715794

#### Phone

+98 61 3336 2414

#### Email

dr\_stellar@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Ahvaz University of Medical Sciences

#### Full name of responsible person

Dr.Badavi Mohammad

#### Street address

Ahvaz University,Golestan Blvd,Dey Ave.

#### City

Ahvaz

#### Province

Khouzestan

#### Postal code

6135715794

#### Phone

+98 61 3336 2414

#### Email

dr\_stellar@yahoo.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

#### Full name of responsible person

Dr.Raeesian Shahrokh

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dentistry

#### Street address

Ahvaz University,Golestan Blvd,Dey Ave.

#### City

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#### Province

Khouzestan

#### Postal code

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#### Phone

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#### Email

dr\_stellar@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Ahvaz University of Medical Sciences

#### Full name of responsible person

Dr.Raeesian Shahrokh

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

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#### Province

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#### Postal code

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#### Phone

+98 61 3336 2414

**Email**

dr\_stellar@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr.Akhtari Marzie

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

Ahvaz University,Golestan Blvd. ,Dey Ave.

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

009833362414

**Email**

dr\_stellar@yahoo.com

**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**

Yes - There is 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Part of the data, which includes soft tissue changes and the amount of impact and adjudication, is published

**When the data will become available and for how long**

1399

**To whom data/document is available**

It will be accessible to everyone

**Under which criteria data/document could be used**

For more statistical analysis and comparison for longer follow-up

**From where data/document is obtainable**

For more information, you can contact Dr. Marzieh Akhtar with the following email dr\_stellar@yahoo.com

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

All emails will be answered within a week

**Comments**