

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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.

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Email

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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.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr.Raeesian Shahrokh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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

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Email

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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

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