

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The comparison of success of using "titanium mesh with buccal advancement flap" for oro-antral fistula closure in compare with "buccal fat pad and buccal advancement flap"

Protocol summary

Study aim

Comparison of the success of simultaneous using titanium mesh and buccal advancement flap with buccal advancement flap simultaneously in OAF closure

Design

A controlled clinical trial, with parallel, randomized groups, on 24 patients. Excel software random function was used for randomization.

Settings and conduct

This clinical trial study will be conducted on patients with OAF who have been referred to the maxillofacial surgery department of Taleghani Hospital from September 2021 to October 2022. Criteria including age, gender, history of smoking, medical and dental history of the patient, and causes of OAF will be recorded in the files. Clinical examinations (maxillary sinusitis and OAF size) and paraclinical investigations (e.g., panoramic radiography and cone beam computed tomography (CBCT)) will be performed. In CBCT, the size of the OAF and the rise in the thickness of the maxillary sinus mucosa will be recorded. In the control group, the OAF in patients will be closed using the buccal fat flap and then by a buccal advancement flap. In the case group, the OAF will be first closed with a titanium mesh and then using an extra buccal advancement flap. Patients will be evaluated clinically at on-week, one-month, three-month, and six-month intervals for infection, swelling, wound dehiscence, and the incidence of OAF.

Participants/Inclusion and exclusion criteria

Patients with OAF over 18 years, symptoms of maxillary sinusitis, American Society of Anesthesiologists (ASA) 1 and 2, OAF larger than 5 mm [7], OLD (one month to 6 months after fistula)

Intervention groups

In the control group, the OAF in patients will be closed using the buccal fat flap and then by a buccal advancement flap. In the case group, the OAF will be first

closed with a titanium mesh and then using an extra buccal advancement flap.

Main outcome variables

infection, swelling, wound dehiscence, and the incidence of OAF

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200922048799N1**

Registration date: **2021-10-03, 1400/07/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-03, 1400/07/11**

Update count: **0**

Registration date

2021-10-03, 1400/07/11

Registrant information

Name

Hamidreza Moslemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of success of using "titanium mesh with buccal advancement flap" for oro-antral fistula closure in compare with "buccal fat pad and buccal advancement flap"

Public title

comparison of oro-antral fistula closure techniques

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with OAF over 18 years, symptoms of maxillary sinusitis, ASA 1 and 2, OAF larger than 5 mm OLD (one month to 6 months after fistula)

Exclusion criteria:

Patients under 18 years, ASA above 2, previous failed treatments, history of microvascular and post-diabetes microvascular, metabolic bone disorders, history of renal failure, head and neck radiotherapy, patients under chemotherapy, pregnancy, drug or alcohol use, poor oral hygiene, periodontal disease, a gingival bleeding index above 20% maxillary fracture, presence of fixation devices or foreign bodies in the sinus, medication-related osteonecrosis of the jaw (MRONJ), or the presence of osteoradionecrosis. patients who refuse to participate in follow-up sessions

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **12****Randomization (investigator's opinion)**

Randomized

Randomization description

simple individual randomization using computer randomization

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti university of medical sciences, Danshjoo BLVD, Velenjak, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2021-07-13, 1400/04/22

Ethics committee reference number

IR.SBMU.DRC.REC.1400.025

Health conditions studied**1****Description of health condition studied**

oro-antral fistula

ICD-10 code

K13.70

ICD-10 code description

Unspecified lesions of oral mucosa

Primary outcomes**1****Description**

wound dehiscence in clinical observation,

Timepoint

one-week, one-month, three-month, and six-month

Method of measurement

clinical observation

2**Description**

infection in clinical observation,

Timepoint

one-week, one-month, three-month, and six-month

Method of measurement

infection signs including edema, erythema, pus or hotness

3**Description**

swelling in clinical observation,

Timepoint

one-week, one-month, three-month, and six-month

Method of measurement

clinical evaluation

4

Description

oro-antral fistula in clinical observation,

Timepoint

one-week, one-month, three-month, and six-month

Method of measurement

clinical evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: titanium mesh and buccal advancement flap

Category

Treatment - Surgery

2

Description

Control group: buccal fat and buccal advancement

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

Pouria Javaheri

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Arabi St., Yemen St , Shahid Chamran Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Tehrani

Street address

Shahid Beheshti School of Dentistry, Danshjo BLVD, Velenjak, Shahid Chamran Highway, Tehran, Iran

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Pouria Javaheri

Position

Resident of oral and maxillofacial surgery

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Tabrizi

Position

Associate Professor in Department of Oral and Maxillofacial Surgery

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

Resident of oral and maxillofacial surgery

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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

There is no further information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

all collected deidentified on demand

When the data will become available and for how long

Starting in April 2022

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

no more intervention or analysis allowed

From where data/document is obtainable

Email to Pouria Javaheri pouriajavaheri1371@gmail.com

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

After the request was accepted by the authors, data will be sent to them.

Comments