Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

Phone

+98 21 4044 3580

Email address

hmoslemi71@gmail.com

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
Age
From **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
Street address
Arabi St., Yemen St , Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2243 9982
Email
pouriajavaheri1371@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Azita Tehranchi
Street address
Shahid Beheshti School of Dentistry, Danshjoo BLVD, Velenjak, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2242 1814
Email
info@sbmu.ac.ir
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
Street address
Shahid Beheshti School of Dentistry, Danshjoo BLVD, Velenjak, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 4044 3580
Email
pouriajavaheri1371@gmail.com

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
Specialist

Other areas of specialty/work
Dentistry

Street address
Shahid Beheshti School of Dentistry, Danshjoo BLVD, Velenjak, Shahid Chamran Highway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 4044 3580

Email
tabmed@gmail.com

Person responsible for updating data

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

Street address
Shahid Beheshti School of Dentistry, Danshjoo BLVD, Velenjak, Shahid Chamran Highway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 4044 3580

Email
pouriajavaheri1371@gmail.com

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