

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Surgical management of nasal septal perforation by mucosal flap rotation and amniotic membrane graft

Protocol summary

Study aim

the effect of amniotic membrane on the success of nasal septal perforation surgery

Design

clinical trial with 12 patients without control group

Settings and conduct

12 patients with symptomatic nasal septum perforation who refer to oral and maxillofacial clinic of Imam reza hospital of Tabriz, will be operated. After hemitransfixion incision, a mucoperichondrial flap will be elevated. In the other side, mucosal rotational flap based on posterior nasal artery will be elevated and suture to perforation borders. Five folded amniotic membrane will be located in mucoperichondrial pocket as an interpositional graft and suture. Patients will be evaluated for perforation closure on one and six month after surgery.

Participants/Inclusion and exclusion criteria

this study will include patients who give informed consent and are ASA I or ASA II and have 2 cm or less nasal septal perforation. we will exclude smokers and drug abusers.

Intervention groups

12 patients with symptomatic nasal septum perforation will be operated. After hemitransfixion incision, a mucoperichondrial flap will be elevated. In the other side, mucosal rotational flap based on posterior nasal artery will be elevated and sutured to the perforation borders. Five folded amniotic membrane will be located in mucoperichondrial pocket as an interpositional graft and sutured. Patients will be evaluated for perforation closure on one and six month after surgery.

Main outcome variables

perforation existence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190513043578N1**

Registration date: **2019-07-30, 1398/05/08**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-30, 1398/05/08**

Update count: **0**

Registration date

2019-07-30, 1398/05/08

Registrant information

Name

Mohsen Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5503

Email address

mohsen.hashemi3263@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Surgical management of nasal septal perforation by mucosal flap rotation and amniotic membrane graft

Public title

Surgical management of nasal septal perforation by

mucosal flap rotation and amniotic membrane graft

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients who give informed consent patients with nasal septum perforation that is 2 cm or less in large diameter ASA I (healthy) and ASA II (with minor systemic disease) patients

Exclusion criteria:

smoker patients drug abuser patients

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 12

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 Tabriz University of Medical Sciences

Street address

Golgasht Ave. Tabriz university of medical sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-11-21, 1397/08/30

Ethics committee reference number

IR.TBZMED.REC.1397.662

Health conditions studied

1

Description of health condition studied

nasal septum perforation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

perforation existence

Timepoint

before surgery and one month after surgery

Method of measurement

inspection

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After general anesthesia and oral intubation, lidocaine 2% with epinephrine 1 100,000 will be injected in septal area . Then, using the hemitransfixion incision, the mucoperichondrial flap will be raised and the edges of the perforation will be cut off with a blade. Before elevating the flap, an aluminum suture envelope will be placed to support the mucoperichondrial flap. Then on the opposite side, the cut from the posterior and lower parts of the septum will begin to elevate mucosal flap, and will continue to the anterior and upper to reach the anterior margin of the perforation. This flap is based on the posterior nasal artery, which is a branch of the sphenopalatine artery. In some cases, releasing the posterior side of the flap will increase the radius of rotation. This flap will cover the edges of the perforation. Amniotic membrane will be provided from the cesarean section of the volunteer patients . This membrane is first completely washed with normal saline and stored in normal saline and one gram cephalixin in the refrigerator at 4 ° C. The amniotic membrane in five layers as an Interpositional graft will be placed in the mucoperichondrial pocket .sutures will be used to fix the membrane and prevent the formation of hematoma. the nose packed for three days.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

oral and maxillofacial clinic of Emam Reza hospital of Tabriz

Full name of responsible person

Mohsen Hashemi

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Mohsen Hashemi

Position

resident

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

No more information

Study Protocol

No - There is not 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