Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 mucoperichondreal 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 mucoperichondreal 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 mucoperichondreal 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 mucoperichondreal 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
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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 mocoperichondrial 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 mucusal 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 cephalexin in the refrigerator at 4 ° C. The amniotic membrane in five layers as an Interpositional graft will be placed in the mucoperichonrial 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Position
resident
Latest degree
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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