

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of antibiotic and application on septalmucosal outcome afterseptoplasty

Protocol summary

Study aim

Effect of antibiotic and splint application on septal mucosal outcome after septoplasty

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, on 90 patients. And the selection of non-random patients was at the discretion of the surgeon

Settings and conduct

the patient that needed septoplasty in Qaem and Emaam Reza hosp. the culture was got from nasal mucosa after surgery and two weeks later and see the efficacy of antibiotic on that and Unilateral blinding was based on the surgeon's discretion to implant the splint

Participants/Inclusion and exclusion criteria

All of the patient between 18 to 65 y old candidate for septoplasty didn't have nasal and sinus surgical history and have no immunocompromised disease

Intervention groups

A group no. 1 that didn't give them antibiotic after septoplasty and the second group get antibiotic after septoplasty and third group that use splint in the surgery and give them antibiotic after that.

Main outcome variables

Amount and kind of mucosal microorganisms before and two weeks after septoplasty in three groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210510051242N1**

Registration date: **2021-06-27, 1400/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-27, 1400/04/06**

Update count: **0**

Registration date

2021-06-27, 1400/04/06

Registrant information

Name

Kianoosh Sedaghat

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3764 3286

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sedaghatk961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of antibiotic and application on septalmucosal outcome afterseptoplasty

Public title

Effect of antibiotic after septoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Negative history of sinus and nasal surgery No immunodeficiency disease

Exclusion criteria:

No operation of patient Infection symptom before surgery
 Receiving antibiotics before surgery Receiving antibiotic 20 days before Cardiovascular risk factor

Age
 From **18 years** old to **65 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **90**

Randomization (investigator's opinion)
 Not randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description
 90 patients are considered as candidates for septoplasty due to septal deviation and nasal obstruction. During the operation, patients who need splints at the surgeon's discretion are considered as a study group and splints are used and after surgery. For this group of oral antibiotics, 500 mg cephalexin capsules are prescribed. Other patients for whom splints have not been used during surgery are assigned to two groups using a random number table. For one group of oral antibiotics, 500 mg of cephalexin capsules are prescribed, and for the control group, according to the opinion of a pharmacist, placebo is used instead of antibiotics. The placebo used is the cocci-ten di-vitamin capsule, which is similar to how antibiotics are used for patients in the treatment group. The placebo used was prepared in collaboration with the pharmaceutical group with a similar appearance to the antibiotic used, which has a complementary aspect and this drug does not have any therapeutic properties. Medications will be given as capsules to patients one hour before surgery .All study groups were generally introduced and explained to the patient , Thus, in case of a faulty injury, a splint needs to be implanted and due to the splint, antibiotics are prescribed, and in case of complete mucosal health and no need to implant a splint, patients in both groups should be prescribed antibiotics and no antibiotics should be prescribed to determine the need. To the drug, in cases where there is no need to implant a split in the healthy mucosa And while the patient agrees to be in one of the groups, with the discretion of the physician while obtaining the written and inserted informed consent, they enter the study . Therefore, due to the nature of the study, the physician in charge of surgery will be aware of the allocation of splints to patients, but patients will not be aware of the use of splints or the type of drug used.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Azadi squ . Eastern door of pardis uni . Medical uni

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Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2020-04-18, 1399/01/30

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.565

Health conditions studied

1

Description of health condition studied

Septal deviation

ICD-10 code

J34.2

ICD-10 code description

Deviated nasal septum

Primary outcomes

1

Description

Mucosal culture after septoplasty

Timepoint

After surgery and 2 weeks later

Method of measurement

Bacterial culture medium

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After septal surgery without splinting, they receive 500 mg of cephalexin oral antibiotic every 6 hours. After surgery and two weeks after the visit, the septum mucosa is cultured. And bacterial growth is compared in two culture media.

Category

Treatment - Drugs

2

Description

Intervention group: The group that is used after splint surgery and receives antibiotics. It is cultured after surgery and two weeks after the visit and removal of the splint from the septal mucosa. And bacterial growth is compared in two culture media.

Category

Treatment - Drugs

3

Description

Control group: Patients who do not receive antibiotics after splint surgery and a culture sample is taken from the septal mucosa after surgery and two weeks after the visit. And bacterial growth is compared in two culture media

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Qaem Hosp

Full name of responsible person

Kianoosh Sedaghat

Street address

Qaem Hosp , Shariati Squ.

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2

Recruitment center

Name of recruitment center

Emam Reza Hosp

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Bashir Rasoulbian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available