Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Effect of antibiotic and application on septalmucosal outcome afterseptoplasty

Protocol summary

Study aim
Effect of antibiotic and splint aplicationon 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 betwen 18 to 65 y old candidate for septoplasty didntn have nasal ans sinus surgical history and have no immunocompromised disease
Intervention groups
A group no. 1 that didnt give them antibiotic after septoplasty and the second gtoup 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 group

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
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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 cpration of patient Infection symptom before surgery Reciving antibiotics before surgery Reciving 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

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Razavi Khorasan

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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
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Sponsors / Funding sources

1

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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
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Position
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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