

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of antibiotic and application on septalmucosal outcome after septoplasty

#### 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)

###### Phone

+98 51 3764 3286

###### Email address

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 after septoplasty

##### 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 splint 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

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Azadi squ . Eastern door of pardis uni . Medical uni

**City**

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

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Qaem Hosp , Shariati Squ.

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**2**

**Recruitment center**

**Name of recruitment center**

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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 Rasoulian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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## Person responsible for scientific inquiries

### Contact

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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