

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Can Prophylactic Postoperative Oral Antibiotic Cause Methicillin Resistant Staphylococcus aureus species (MRSA) in Septoplasty or Rhinoplasty?

Protocol summary

Methicillin resistant staphylococcus aureus species

Study aim

Can Prophylactic Postoperative Oral Antibiotic Cause Methicillin Resistant Staphylococcus aureus species in Septoplasty or Rhinoplasty?

Design

In a double-blind randomized clinical trial 102 patients who were candidates for septoplasty or rhinoplasty were divided into intervention and control groups. The intervention group received a preoperative injection of cephalothin (1 g) and postoperative oral cephalexin (500 mg 4 times a day for 7 days). The control group only received preoperative injection of cephalothin (1g). In studied patients, vestibular nasal swab were cultured preoperatively and on 7th postoperative day. Then, the samples were transferred quickly to the laboratory to detect methicillin resistant staphylococcus aureus species.

Settings and conduct

In a double-blind randomized clinical trial 102 patients who were candidates for septoplasty or rhinoplasty were divided into two intervention and control groups. The intervention group received a preoperative injection of cephalothin (1 g) and postoperative oral cephalexin (500 mg 4 times a day for 7 days). The control group only received preoperative injection of cephalothin (1g).

Participants/Inclusion and exclusion criteria

Exclusion criteria: patients with any type of immune deficiencies; upper respiratory infection; any history of antibiotic usage in last 3 months; any hospital admission during last year; any history of allergic reaction to cephalexin. Inclusion criteria: Patients known to be at risk for Methicillin resistant Staphylococcus aureus species colonization and infection after rhinoplasty.

Intervention groups

The control group only received preoperative injection of cephalothin (1g). The case group received a preoperative injection of cephalothin (1 g) and postoperative oral cephalexin (500 mg 4 times a day for 7 days).

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140618018143N4**

Registration date: **2018-12-09, 1397/09/18**

Registration timing: **retrospective**

Last update: **2018-12-09, 1397/09/18**

Update count: **0**

Registration date

2018-12-09, 1397/09/18

Registrant information

Name

nader akbari dilmaghani

Name of organization / entity

shahid beheshti medical university

Country

Iran (Islamic Republic of)

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+98 21 5541 9005

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2014-08-30, 1393/06/08

Actual recruitment start date

2013-06-22, 1392/04/01

Actual recruitment end date

2014-08-30, 1393/06/08

Trial completion date

2014-08-30, 1393/06/08

Scientific title

Can Prophylactic Postoperative Oral Antibiotic Cause Methicillin Resistant Staphylococcus aureus species (MRSA) in Septoplasty or Rhinoplasty?

Public title

Methicillin Resistant Staphylococcus aureus species in Septoplasty or Rhinoplasty

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients known to be at risk for Methicillin Resistant Staphylococcus aureus species colonization and infection after surgery

Exclusion criteria:

Age older than 60 years old HIV Those with recent hospital admission Those with recent antibiotic use Immunodeficiency Upper respiratory infection

Age

To 60 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 102

Actual sample size reached: 98

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Surgeon and the patients were blind to the groups' allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Yaman

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2013-04-26, 1392/02/06

Ethics committee reference number

SBMU.REC.1392.26

Health conditions studied**1****Description of health condition studied**

Septoplasty or Rhinoplasty

ICD-10 code

J00

ICD-10 code description

Acute nasopharyngitis [common cold]

Primary outcomes**1****Description**

Detection of methicillin resistant staphylococcus aureus species

Timepoint

Preoperative and on 7th day postoperative

Method of measurement

The samples were cultured onto a mannitol salt agar medium for isolation of S. aureus and then incubated at 35°C overnight. The isolated bacteria were identified based on morphologic and biochemical tests. Isolated staphylococcus aureus were screened for methicillin-resistance.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: This group received a preoperative injection of cephalothin (1 g) and postoperative oral cephalixin (500 mg 4 times a day for 7 days).

Category

Treatment - Drugs

2**Description**

Control group: The control group only received preoperative injection of cephalothin (1g).

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Nader Akbari Dilmaghani

Street address

Loghman Hakim Hospital, Makhsus St, Lashkar
Crossload, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Deputy of Research Center, Shahid Besheshti
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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

Shahid Beheshti 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

2

Sponsor

Name of organization / entity

معاونت پژوهشی دانشگاه علوم پزشکی شهید بهشتی

Full name of responsible person

Nader Akbari Deilamghani

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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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nader Akbari Dilmaghani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some parts of data related to main result can be shared.

When the data will become available and for how long

After published

To whom data/document is available

Academic Researchers

Under which criteria data/document could be used

Clinicians

From where data/document is obtainable

Email

What processes are involved for a request to access data/document

A week after receiving a request

Comments