Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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 itntervention 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 itwo ntervention 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

Methicillin resistant staphylococcus aureus species

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)

Phone

+98 21 5541 9005

Email address

nadakbari@sbmu.ac.ir

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
Ŝurgeon 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 cephalexin (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

Treatment - Drugs

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
Seyed Ali Ziaee

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Deputy of Research Center, Shahid Besheshti University, Shahid Abbas Erabi St. Yamn St. Chamran Highway

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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

Contact
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Ear, Nose, and Throat
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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