Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Use of azelastine and sodium chloride for prevention of sinusitis in ICU admitted patients

Protocol summary

Study aim
The primary end-point of this study was to investigate the incidence of sinusitis confirmed by imaging between the two treatment groups.
Design
Randomized, parallel, and open label trial
Settings and conduct
The present randomized, parallel, and open label trial was conducted in patients admitted to ICU at Imam Reza Hospital between September 2017 to September 2018.
Participants/Inclusion and exclusion criteria
Patients aged more than 18 years during the first 24 hours after Nasogasteric (NG) tube insertion were randomized into either the treatment or control group. Patients with the following criteria were excluded from the study: trauma to the head and face or anatomical abnormalities preventing NG tube placement; history of sinusitis in the last three months; leukopenia (WBC <3500 / ml); coagulation disorders (Platelet<100000 / ml, International Normalized Ratio> 1.5 or Prothrombin time test more than two times higher than normal); the presence of a tumor in the patient's head and neck.
Intervention groups
Intervention group: In the treatment group for patients, every 12 hours, a puff of 0.15% Azlestine spray and 0.65% sodium chloride per nostril are prescribed. Control group: In the control group, routine care was performed for patients.
Main outcome variables
Main outcome variable: Incidence of sinusitis confirmed by imaging

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190312043037N1**
Registration date: **2019-04-20, 1398/01/31**
Registration timing: **retrospective**

Last update: **2019-06-30, 1398/04/09**
Update count: **1**
Registration date
2019-04-20, 1398/01/31

Registrant information
Name
amirebrahim miroliaie
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 4347 3700
Email address
aam_thunderbird@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-09-01, 1396/06/10
Expected recruitment end date
2018-09-30, 1397/07/08
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Use of azelastine and sodium chloride for prevention of sinusitis in ICU admitted patients

Public title
Prevention of sinusitis
Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged more than 18 years during the first 24 hours after Nasogasteric tube insertion were randomized into either the treatment or control group.

Exclusion criteria:

Trauma to the head and face or anatomical abnormalities preventing Nasogasteric tube placement. History of sinusitis in the last three months. Leukopenia (white blood cell<3500 / ml) Coagulation disorders (platelet<100000 / ml, International Normalized Ratio (INR)> 1.5 or Prothrombin time test (PTT) more than two times higher than normal) Presence of a tumor in the patient's head and neck

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using the simple randomization method.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Artesh University of Medical Sciences

Street address

Artesh University of Medical Sciences, Etemadzadeh street, Fatemi street

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2017-08-01, 1396/05/10

Ethics committee reference number

IR.AJAUMS.REC.1396.72

Health conditions studied

1

Description of health condition studied

Sinusitis

ICD-10 code

J01

ICD-10 code description

Acute sinusitis

Primary outcomes

1

Description

The percentage of patients at the end of the study in both treatment and control groups with imaging confirmed sinusitis.

Timepoint

During 10 days of tial

Method of measurement

Body temperature test using digital thermometer, laboratory test for white blood cell count, examination of throat secretions by the physician, and confirmation of diagnosis by Computed Tomography scan

Secondary outcomes

1

Description

Incidence of pneumonia

Timepoint

During the 10 days of study

Method of measurement

Evaluation by CPIS score

2

Description

Changes in CPIS score

Timepoint

During the 10 days of study

Method of measurement

Evaluation by CPIS score

3

Description

White blood cell changes in patients during the study

Timepoint

During the 10 days of study

Method of measurement

Laboratory examination of white blood cells

4

Description

Changes in patient body temperature during the study

Timepoint
During the 10 days of study
Method of measurement
Checking body temperature by digital thermometer

5

Description
Changes in tracheal and secretions of patients
Timepoint
During the 10 days of study
Method of measurement
Qualitative assessment by the doctor

6

Description
Evaluation of isolated organisms from the patient's' tracheal secretions
Timepoint
During the 10 days of study
Method of measurement
Microbial culture of tracheal secretion

Intervention groups

1

Description
Intervention group: In the treatment group for patients, every 12 hours, a puff of 0.15% Azlestine spray and 0.65% sodium chloride per nostril are prescribed.
Category
Prevention

2

Description
Control group: In the control group, routine care was performed for patients.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Ebrahim Hazrati
Street address
Artesh University of Medical Sciences, Etemadzadeh street, Fatemi street
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 4382 2274
Email
dr.hazrati.e@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mostafa Shahrezayee
Street address
Etemadzadeh street, Fatemi street
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 4382 2274
Email
moshahrezayee@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Ebrahim Hazrati
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Etemadzadeh street, Fatemi street
City
Tehran
Province

Tehran
Postal code
1411718541
Phone
+98 21 4382 2274
Email
dr.hazrati.e@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Ebrahim Hazrati
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Etemadzadeh street, Fatemi street
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 4382 2274
Email
dr.hazrati.e@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Ebrahim Hazrati
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Etemadzadeh street, Fatemi Street
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 4382 2274
Email
dr.hazrati.e@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
This information is confidential and can not be provided
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All available data will be provided
When the data will become available and for how long
starting 12 months after publication
To whom data/document is available
Academic staff and researchers
Under which criteria data/document could be used
No more permission will be given
From where data/document is obtainable
By email researcher
What processes are involved for a request to access data/document
Provide an explanation in the email for the reason for requesting information from the researcher
Comments