

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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 Nasogastric (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% Azelastine 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 Nasogastric tube insertion were randomized into either the treatment or control group.

Exclusion criteria:

Trauma to the head and face or anatomical abnormalities preventing Nasogastric 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 trial

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% Azlesthine 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

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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

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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

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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Other areas of specialty/work

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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