Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation effects of nebulaized gentamycin in COPD-exacerbation

Protocol summary

Summary

The main purpose of this study is to investigate the effect of nebulaized gentamycin in treatment of COPD flare attacks referred to the Shahrekord hospitals of Kashani and Hajar. This study design is not blinded clinical trial, considered population includes patients older than forty years with a diagnosis of COPD flare attacks, admitted to the Shahrekord hospitals of Kashani and Hajar. The number of patients studied is 82, they randomly are divided into 2 groups of 41 people of case and control. In the case group, the gentamicin injection of 80 mg mixed with 2 cc normal saline use by nebulizer, twice a day for 5 days. In the control group routine treatment is done and not use nebulized gentamycin. Inclusion criteria: absence of renal failure; lack of sensitivity to gentamicin. Exclusion criteria: heart disease; renal failure; cancer; bronchiectasis and sensitivity to gentamicin. Primary outcome include o2sat, lung volumes and capacity and white blood cells and secondary outcome include Dyspnea will be measured before and 7 days after the intervention and evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081723659N1**
Registration date: **2015-10-19, 1394/07/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-10-19, 1394/07/27

Registrant information

Name
Shahin Asgari Savadjani
Name of organization / entity
Shahrekord University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahrekord University of Medical Sciences

Expected recruitment start date

2014-02-19, 1392/11/30

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation effects of nebulaized gentamycin in COPD-exacerbation

Public title

Effects of nebulaized gentamycin in COPD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: absence of renal failure; lack of sensitivity to gentamicin; no cancer; no bronchiectasis; no heart disease; grade 1, 2 and 3 Exclusion criteria: heart disease; kidney failure; cancer; bronchiectasis; pulmonary infection; other; sensitivity to gentamicin; Grid 4.

Age

From **40 years** old to **90 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **82**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
In this study sampling method is a table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences
Street address
Shahrekord University of Medical Sciences, Rahmatie, Shahrekord
City
Shahrekord
Postal code
Approval date
2014-02-16, 1392/11/27
Ethics committee reference number
92-10-10

Health conditions studied

1

Description of health condition studied
Chronic Obsructive Pulmonary Disease
ICD-10 code
J44.9
ICD-10 code description
Choronic Obstructive Pulmonary Diseases

Primary outcomes

1

Description
o2sat
Timepoint
Before and after the intervention.
Method of measurement
Pulse Oximetery

2

Description
Lung volumes and capacity
Timepoint
Before and after the intervention.
Method of measurement
Spirometry

3

Description
White blood cells
Timepoint
Before and after the intervention.
Method of measurement
Lab data

Secondary outcomes

1

Description
Dyspnea
Timepoint
Before and after the intervention
Method of measurement
Borg Scale

Intervention groups

1

Description
Intervention group 1: In the case group, the gentamicin injection of 80 mg mixed with 2 cc normal saline use by nebulizer, twice a day for 5 days.
Category
Treatment - Drugs

2

Description
Intervention group1: In the control group routine treatment is done and not use nebulized gentamycin.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar hospital of Shahrekord
Full name of responsible person
Shaheen Askari Savadjani
Street address
Hajar hospital, Parastar Street, Shahrekord

City
Shahrekord

2

Recruitment center
Name of recruitment center
Shahrekord kashani hospital
Full name of responsible person
Dr Forough Soltani Nejad
Street address
Kashani hospital, Parastar Street, Shahrekord
City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahrekord University of Medical Sciences
Full name of responsible person
Dr Mahmoud Mobasheri
Street address
Vice Chancellor for research, Shahrekord University of Medical Sciences, Kashani Street, Shahrekord
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahrekord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahrekord University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty