

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 38 3363 2358

Email address

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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 Obstructive Pulmonary Disease

ICD-10 code
J44.9

ICD-10 code description
Chronic Obstructive Pulmonary Diseases

Primary outcomes

1

Description
o2sat

Timepoint
Before and after the intervention.

Method of measurement

Pulse Oximetry

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

Full name of responsible person
Shaheen Askari Savadjani

Position
Resident of Internal Medicine

Other areas of specialty/work

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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