Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the effectiveness of nebulized Budezonide (pulmicort) versus placebo in the treatment of adult with moderate to severe acute asthma referring to Dr Shariati and Sina hospitals from 2017 to 2018

Protocol summary

Study aim

Comparison of the effectiveness of nebulized Budezonide (pulmicort)versus placebo in the treatment of moderate to sever acute asthma referring to Dr Shariati and Sina hospital from 2017-2018

Design

double blind randomized clinical trial, all patients divided into two groups each group consist 20 patients

Settings and conduct

This is a double blind, randomized clinical trial in shariati and sina hospitals. All patients in both group would receive the standard treatment of asthma (o2,beta 2 agonist inhaler, anti cholinergic inhaler and systemic corticosteroids,100mg hydrocortison) then patients will randomly divided into 2 groups. in the first group, nebulized budezonide (pulmicort) will be administered with the dose of 0.5 mg every half an hour up to 3 doses and in the second group nebulized normal saline (placebo) will be administered with the dose of 3 cc in every half an hour up to 3 doses then we will compare and evaluate the patients vital signs(PR,RR,O2saturation), VBG, lung physical examination, any evidence of respiratory distress, the time of patients response to treatment, their wheezing relief, patients satisfaction and physical satisfaction. We will compare all these variables during 30, 60,180 min after treatment. We also want to determine patients disposition, length of hospital stay, recurrence rate and readmission rate in one month later.

Participants/Inclusion and exclusion criteria

known case of asthma that have moderate to sever acute asthma attack and who are older than 18 years old and also signed informed consent letter to participate in the study

Intervention groups

Nebulized Budezonide (Pulmicort) with the dose of 0.5 mg every half an hour up to 3 doses in the intervention group. Nebulized Normal salin (placebo) in 3 doses(3 cc) in the control group.

Main outcome variables

recovery (response to treatment) of clinical symptom of acute asthma from the physician's and patient's view; recurrence rate and readmission rate of patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170325033132N3**
Registration date: **2018-02-18, 1396/11/29**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-18, 1396/11/29**
Update count: **0**

Registration date

2018-02-18, 1396/11/29

Registrant information

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maryam Habibi Samadi
Name of organization / entity
Tehran University Medical sciense
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date
2018-03-21, 1397/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of nebulized Budezonide (pulmicort) versus placebo in the treatment of adult with moderate to severe acute asthma referring to Dr Shariati and Sina hospitals from 2017 to 2018

Public title
The nebulized Budezonide (pulmicort) effectiveness in acute adult asthma attack
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age > 18 with signed informed consent letter Patients with acute asthma(moderate to severe)
Exclusion criteria:
Unwillingness of patients to participate in the study Patients with COPD Pneumonia Pneumothorax CHF Acute and severe respiratory failure with cyanosis and confusion Loss of consciousness Pregnant patients Smokers Intubated patients and patients with unstable vital signs New case of asthma Hemodynamic instability
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
random no. 4 blocks
Blinding (investigator's opinion)
Double blinded
Blinding description
There is a closed pocket for drug or placebo in the hand of triage nurse and randomly she/he give the pocket to the patients. Both of the patient and doctor don't know about drug/placebo but triage nurse alert about the drug or placebo which specify to any patient. Drug/placebo in the same form with the same dose injected to the patient.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran university of medical sciences
Street address
Tehran university of medical sciences , Qods St, Keshavarz Blvd, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1411713135
Approval date
2016-10-25, 1395/08/04
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1395.859

Health conditions studied

1

Description of health condition studied
asthma
ICD-10 code
J45.51
ICD-10 code description
Severe persistent asthma with (acute) exacerbation

Primary outcomes

1

Description
improvement of vital sign and clinical symptoms in patients with asthma attack
Timepoint
At the begining of the study(before intervention), 30, 60, 180 minutes after treatment
Method of measurement
physical exam

Secondary outcomes

1

Description
Relief of acute asthma attack(sign and symptom)from patient and dr "view
Timepoint
During the treatment in emergency center
Method of measurement
by completing questionnaire form, follow up, ask question about the number of readmission rate and

length of hospitalization

Intervention groups

1

Description
Intervention group: patients with acute asthma, nebulized budezonide(pulmicort) will be administered with the dose of 0.5 mg every half an hour up to three dose in additional standard treatment of asthma
Category
Treatment - Drugs

2

Description
Control group: patients with acute asthma, nebulized normal salin (placebo)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati and Sina hospital
Full name of responsible person
maryam habibi samadi
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dr shariati hospital, jalal aleahmad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Astra Zeneca
Full name of responsible person
Elnaz Vahidi
Street address
dr shariati hospital, North Karegar, Jalal Aleahmad
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Email
maryamhabibi2011@yahoo.com
Web page address
http://shariati.tums.ac.ir/cpages/mainpage.asp?l=S1M5P2C1
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Astra Zeneca
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
maryam habibi samadi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
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Person responsible for scientific inquiries

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resident

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Person responsible for updating data

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Position
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Latest degree
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Other areas of specialty/work
Emergency Medicine

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Web page address
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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
all of the data after hiding personal information

When the data will become available and for how long
6 months after publishing

To whom data/document is available
researchers in universities

Under which criteria data/document could be used
everybody who access the open access journals

From where data/document is obtainable
Dr Elnaz VAhidi Dr Maryam Habibi Samadi Dr Shariati hospital, North karegar, jalalealeahmad

What processes are involved for a request to access data/document
supplemental file

Comments