

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 severe 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 (α_2 , β_2 agonist inhaler, anti cholinergic inhaler and systemic corticosteroids, 100mg hydrocortison) then patients will randomly divided into 2 groups. in the first group, nebulized budesonide (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, O_2 saturation), 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 severe 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 Budesonide (Pulmicort) with the dose of 0.5 mg every half an hour up to 3 doses in the intervention

group. Nebulized Normal saline (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

Name

maryam Habibi Samadi

Name of organization / entity

Tehran University Medical science

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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 budesonide(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 saline (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

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dr shariati hospital, North Karegar, Jalal Aleahmad

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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

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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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