Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of the Treatment With Budesonide Nebuliser among Patients with Acute Asthma

Protocol summary

Study aim
The effectiveness of the Treatment With Budesonide Nebuliser among Patients with Acute Asthma
Design
Two arm parallel group randomized trial with blinded postoperative care and outcome assessment
Settings and conduct
the current clinical trial study will be conducted on patients with acute Asthma who referred to the Emergency Department of a hospital. On arrival Peak expiratory flow(PEF) of all individuals will be measured. Patients will be classified into two groups with a different type of medicine. they will take medicine several times. After receiving each dose, the PEF will be measured. Finally, the average of PEF and the duration of admission will be compared between two groups.
Participants/Inclusion and exclusion criteria
Inclusion criteria :Patients with Acute Asthma ,Definitive diagnosis of asthma ,being older than 18 Exclusion criteria the Flu ,Patients who are treated with other forms of medication ,Pregnant patients ,obvious infection in Chest X-ray ,Patient with heart, kidney, liver disease
Intervention groups
receiving Below items through nebulizer: Control group: Oxygen, spray containing Salbutamol and Ipratropium bromide, corticosteroids in the form of hydrocortisone + distilled water intervention group: Oxygen, spray containing Salbutamol and Ipratropium bromide, corticosteroids in the form of hydrocortisone + budesonide
Main outcome variables
PEF hospitalization duration

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170531034256N2**
Registration date: **2019-05-27, 1398/03/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-27, 1398/03/06**
Update count: **0**
Registration date
2019-05-27, 1398/03/06

Registrant information
Name
Atefeh Abedini
Name of organization / entity
Chronic Respiratory Diseases Research Center, National Research Institute of Tuberculosis and Lung D
Country
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-03-21, 1398/01/01
Expected recruitment end date
2019-09-23, 1398/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of the Treatment With Budesonide Nebuliser among Patients with Acute Asthma

Public title
Effectiveness of the Treatment With Budesonide Nebuliser among Patients with Acute Asthma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of asthma being older than 18
Exclusion criteria:
the Flu Patients who are treated with other forms of medication Pregnant patients obvious infection in Chest X-ray Patient with heart , kidney, liver disease
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are randomly assigned to one of two study groups with the help of a random number table and receive the intervention of the same group.
Blinding (investigator's opinion)
Double blinded
Blinding description
*A statistician will classify the patients based on the random numbers in either group one (control group) or group 2 (intervention group). This person is unaware of the type of treatment which they will receive in each group. * Patients will be informed about two potential types of treatment but they won't know they will receive which of those. * The nurse will give the patients' unlabeled medicine based on their code.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of National Research Institute of Tuberculosis and Lung Diseases (NRITLD), Shahid B Masih Daneshvari Hospital, DAR ABAD
City
Tehran
Province
Tehran
Postal code
19569-44413
Approval date
2019-02-04, 1397/11/15
Ethics committee reference number
IR.SBMU.NRITLD.REC.1397.064

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
J45.21
ICD-10 code description
Mild intermittent asthma with (acute) exacerbation

Primary outcomes

1

Description
Peak expiratory flow
Timepoint
0 min, 30 min, 60 min, 90 min
Method of measurement
Peak Flow Meter

2

Description
hospitalization duration
Timepoint
final
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: On arrival, PEF of all individuals will be evaluated. The so-called intervention group will receive Oxygen, the spray containing Salbutamol and Ipratropium bromide, corticosteroids in the form of hydrocortisone based on Gina guideline in addition to budesonide (at the arrival, 0.5-ml budesonide will be taken and this will be repeated every 30 minutes for three times) using a nebulizer.
Category
Treatment - Drugs

2

Description
Control group: On arrival, PEF of all individuals will be evaluated. The so-called control group will receive Oxygen, the spray containing Salbutamol and Ipratropium bromide, corticosteroids in the form of hydrocortisone based on Gina guideline in addition to distilled water (at the arrival, 0.5-ml distilled water will be taken and this will be repeated every 30 minutes for three times) using a nebulizer.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
the Emergency Department of Masih Daneshvari Hospital

Full name of responsible person
Atefeh Abedini

Street address
Masih Daneshvari hospital, Dar Abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Fatemeh Razavi

Position
Researcher

Latest degree
Master

Other areas of specialty/work
Pulmonology

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Person responsible for scientific inquiries

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Shahid Beheshti University of Medical Sciences

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Associate professor

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Subspecialist

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Person responsible for updating data

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Atefeh Abedini
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Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available