Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of clinical and peak expiratory flow rate of nebulization of Albuterol and Heliox (helium 70%,oxygen 20%) versus nebulization of Albuterol and Oxygen during acute asthma exacerbation

Protocol summary

Summary

Goal: Evaluation of the effect of clinical and peak expiratory flow rate of nebulization of Albuterol and Heliox (helium 70%,oxygen 20%) versus nebulization of Albuterol and Oxygen during acute asthma exacerbation. Trial Study will be done on 96 patients in intervention and control groups, we'll give Heliox in addition to standard treatment to the intervention group and so the control group will receive standard treatment. Inclusion Criteria: Acute Asthma Attack with minimum of 18 years old and maximum of 55year; Exclusion Criteria: History of Smoking more than 10 pack/ years; History of chronic bronchitis; acute medical problem; History of Cardiovascular Diseases; cardiac arythmia; Pregnant women; treatment with nebulization of beta agonist during 6 hours ago. results of FEV1,PEFR and clinical states will be analyzed between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100715446N6**
Registration date: **2015-11-06, 1394/08/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-11-06, 1394/08/15

Registrant information

Name

Hassan Motamed

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of clinical and peak expiratory flow rate of nebulization of Albuterol and Heliox (helium 70%,oxygen 20%) versus nebulization of Albuterol and Oxygen during acute asthma exacerbation

Public title

Evaluation of heliox efficacy in acute asthma attack

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Acute Asthma Attack with minimum of 18 years old and maximum of 55year; Exclusion Criteria: History of Smoking more than 10 pack/ years; History of chronic bronchitis; acute medical problem; History of Cardiovascular Diseases;cardiac arythmia; Pregnant women; treatment with nebulization of beta agonist

during 6 hours ago.

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Research Assistant, Next to central Building, Ahvaz Jundishapur University of Medical Sciences, University town

City
Ahvaz

Postal code
61357-15794

Approval date
2015-08-25, 1394/06/03

Ethics committee reference number
IR.AJUMS.REC.1394.303

Health conditions studied

1

Description of health condition studied
Acute attack asthma

ICD-10 code
J45

ICD-10 code description
Asthma

Primary outcomes

1

Description
Clinical state

Timepoint
Before intervention 20,40,60 minutes after intervention

Method of measurement
Base on alert status,talking,wizing,use of respiratory muscles

2

Description
Forced Expiratory Volum in First Second (FEV1)

Timepoint
Before intervention 20,40,60 minutes after intervention

Method of measurement
Mililiter with use of Peak Flow Meter

3

Description
Peak Expiratory Flow Rate(PEFR)

Timepoint
Before intervention 20,40,60 minutes after intervention

Method of measurement
Mililiter with use of Peak Flow Meter

Secondary outcomes

1

Description
Blood pressure

Timepoint
Before intervention 20,40,60 minutes after intervention

Method of measurement
mm Hg

2

Description
Pulse Rate

Timepoint
Before intervention 20,40,60 minutes after intervention

Method of measurement
Rate/Minutes

3

Description
Respiratory Rate

Timepoint
Before intervention 20,40,60 minutes after intervention

Method of measurement
Rate/Minutes

4

Description
Saturation of arterial blood oxygen (SO2 %)

Timepoint
Before intervention 20,40,60 minutes after intervention
Method of measurement
with Pulse Oximetry

5

Description
Pulsus Paradox
Timepoint
Before intervention 20,40,60 minutes after intervention
Method of measurement
10 reduse of Blood Pressure during inspiration

Intervention groups

1

Description
Intervention Group: Salbutamol 2.5mg each 20 minutes via nebulizer Atrovent 2.5mg each 20 minutes 3 times during 60 minutes via oral Prednisolone 50mg one time.Heliox accompanying Albuterol 10 mil/lit nebulized each 20 minutes 3 times during 60 minutes.in all of patients measure and record Clinical State,FEV1,PEFR before intervention and 20,40,60 minutes after intervention.BP,PR,RR,PP,SO2% measure and record too.
Category
Treatment - Drugs

2

Description
Control Group: Salbutamol 2.5mg each 20 minutes with nebulizer Atrovent 2.5mg each 20 minutes 3 times during 60 minutes with oral Prednisolone 50mg one time.Clinical State,FEV1,PEFR measure and record before intervention and 20,40,60 minutes intervention.BP,RR,PR,PP,S02% measure and record too.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Golestan Hospital
Full name of responsible person
Dr. Hasan Motamed
Street address
Ahvaz, golestan street, Ahvaz Golestan Hospital
City
Ahvaz

2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr. Hasan Motamed
Street address
Imam Khomeini Hospital , 24 metri street, Ahvaz
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chanceller for research,Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Nader Saki
Street address
Research Assistant,Next to center Building, Ahvaz Jundishapur University of Medical Sciences, University town
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chanceller for research,Ahvaz Jundishapur 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
Ahvaz Golestan Hospital
Full name of responsible person
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Emergency Medicine Assistant Professor
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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