

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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 arrhythmia; 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

Emergency Department , Ahvaz Jundishapur University of Medical Sciences , Ahvaz , Iran

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3079

Email address

motamed-h@ajums.ac.ir

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 arrhythmia; 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 reduce 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,SO2% 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 chancellor 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 chancellor 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

Dr. Hasan Motamed

Position

Emergency Medicine Assistant Professor

Other areas of specialty/work**Street address**

Ahvaz Golestan Hospital,Golestan street,Ahvaz

City

Ahvaz

Postal code**Phone**

+98 61 3374 3079

Fax**Email**

Hasan_motamed@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Golestan Hospital

Full name of responsible person

Dr. Hasan Motamed

Position

Emergency Medicine Assistant Professor

Other areas of specialty/work

Street address

Ahvaz Golestan Hospital, Golestan street, Ahvaz

City

Ahvaz

Postal code

613573318

Phone

+98 61 3374 3079

Fax

Email

Hasan_motamed@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Golestan Hospital

Full name of responsible person

Dr. Hasan Motamed

Position

Emergency Medicine Assistant Professor

Other areas of specialty/work

Street address

Ahvaz Golestan Hospital, Golestan street, Ahvaz

City

Ahvaz

Postal code

613573318

Phone

+98 61 3374 3079

Fax

Email

Hasan_motamed@yahoo.com

Web page address

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