Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparing the effect of Alprostadil administration with routine cares on improvement of forced expiratory volume in 1 second, peak expiratory flow rates and clinical indexes of patients with acute asthma attack

Protocol summary

Summary

Objective: assessment the effect of Alprostadil on improvement of forced expiratory volume in 1 second, peak expiratory flow rate and clinical indexes of acute asthma attack. Design: in this double blind clinical trial, both patients and analyzer will unaware of group's assignment. Randomization: patients will be allocated to two equal groups of intervention and control according to table of random numbers. Main outcome measures (variables): forced expiratory volume in 1 second, peak expiratory flow rate and clinical indexes. Setting and conduct: outcome measures will be assessed before intervention and in 20, 40, and 60 minutes after intervention in both groups. Participants including major eligibility criteria: this study will conduct on 28 patients with acute asthma attack in Ahvaz Imam and Gholestan hospitals. Main inclusion criteria include age range of 18 to 65 years and proved diagnosis of asthma based on primary outcomes (wheezing, cough, and breathlessness triad) and main exclusion criteria include pulmonary diseases similar to asthma (such as interstitial lung disease); having proven coagulation disorders and being treated with anticoagulants; history of chronic bronchitis; having acute medical disorders, cardiac, coronary vascular and arrhythmia diseases; being pregnant; treating with beta agonist nebulizers during last 6 hours; using cigarette more than 10 packs in year. Intervention: patients in control group will receive treatment based on their asthma attack severity. In mild to moderate attacks, patients will receive 2.5 mg Albuterol and 0.5 mg Ipratropium Bromide via inhalation with 20 minutes interval in three dosages. Patients with severe asthma attack will receive 5 mg Albuterol and 0.5 mg Ipratropium Bromide via inhalation with 20 minutes interval in three dosages, and will receive Prednisolone via oral. Patients in intervention group will receive 2 mcg/kg/min intravenous Alprostadil and Albuterol via inhalation with 20 minutes interval in three dosages.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052828129N1**
Registration date: **2016-06-05, 1395/03/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-06-05, 1395/03/16

Registrant information

Name

Azin Moradi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahwaz Judishapur University of Medical Sciences

Expected recruitment start date

2016-04-27, 1395/02/08

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of Alprostadil administration with routine cares on improvement of forced expiratory volume in 1 second, peak expiratory flow rates and clinical indexes of patients with acute asthma attack

Public title
The effect of Alprostadil on improvement of acute asthma attack
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age range of 18 to 65 years; proved diagnosis of asthma based on primary outcomes (wheezing, cough, and breathlessness triad). Exclusion criteria: pulmonary diseases similar to asthma (such as interstitial lung disease)؛ having proven coagulation disorders and being treated with anticoagulants؛ history of chronic bronchitis; having acute medical disorders, cardiac, coronary vascular and arrhythmia diseases؛ being pregnant; treating with beta agonist nebulizers during last 6 hours, using cigarette more than 10 packs in year.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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 Ahwaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan
City
Ahvaz
Postal code
Approval date
2016-04-26, 1395/02/07
Ethics committee reference number
IR.AJUMS.REC.1395.44

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
J45.8
ICD-10 code description
Mixed asthma

Primary outcomes

1

Description
Forced expiratory volume in 1 second
Timepoint
Before intervention and in 20, 40, and 60 minutes after intervention
Method of measurement
Researcher-made questionnaire

2

Description
Peak expiratory flow rate
Timepoint
Before intervention and in 20, 40, and 60 minutes after intervention
Method of measurement
Researcher-made questionnaire

3

Description
Clinical symptoms severity
Timepoint
Before intervention and 40 minutes after intervention
Method of measurement
Researcher-made questionnaire

Secondary outcomes

1

Description
Respiratory rate
Timepoint
Before intervention and 40 minutes after intervention
Method of measurement

Researcher-made questionnaire

2

Description
Pulse rate
Timepoint
Before intervention and 40 minutes after intervention
Method of measurement
Researcher-made questionnaire

3

Description
Blood pressure rate
Timepoint
Before intervention and 40 minutes after intervention
Method of measurement
Researcher-made questionnaire

4

Description
Atrial oxygen saturation
Timepoint
Before intervention and 40 minutes after intervention
Method of measurement
Researcher-made questionnaire

5

Description
Level of consciousness
Timepoint
Before intervention and 40 minutes after intervention
Method of measurement
Researcher-made questionnaire

6

Description
Wheezing
Timepoint
Before intervention and 40 minutes after intervention
Method of measurement
Borg dyspnea scale

7

Description
Using respiratory peripheral muscles
Timepoint
Before intervention and 40 minutes after intervention
Method of measurement
Borg dyspnea scale

Intervention groups

1

Description
Patients in intervention will receive 2 mcg/kg/min intravenous Alprostadil and Albuterol with 20 minutes interval in three dosages via inhalation.
Category
Treatment - Drugs

2

Description
Patients in control group will receive treatment based on their asthma attack severity. In mild to moderate attacks, patients will receive 2.5 mg Albuterol and 0.5 mg Ipratropium Bromide via inhalation with 20 minutes interval in three dosages. Patients with severe asthma attack will receive 5 mg Albuterol and 0.5 mg Ipratropium Bromide via inhalation with 20 minutes interval in three dosages, and will receive Prednisolone via oral.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Emam Khomeini hospital
Full name of responsible person
Azin Moradi
Street address
Emam Khomeini hospital, Ahvaz, Khuzestan
City
Ahvaz

2

Recruitment center
Name of recruitment center
Ahvaz Golestan hospital
Full name of responsible person
Azin Moradi
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Golestan hospital, Golestan road, Ahvaz, Khuzestan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ahwaz Judishapur University of Medical Sciences
Full name of responsible person
Nader Saki
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan
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, Ahwaz Judishapur 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 Jundishapur University of Medical Sciences
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Position
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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