Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of High-Flow Oxygen Therapy on clinical and spirometry findings in Acute Exacerbation of Asthma

Protocol summary

Summary

Objectives: This study compared high flow oxygen therapy and oxygen at low flow in patients with acute asthma attack admitted in the emergency department. Design: A prospective double-blind trial pilot study was designed Method: patients randomly assigned to groups, high flow oxygen therapy and low flow oxygen therapy. Both groups receive other treatments for asthma attack. Outcome variables before, 2 hours and 24 hours after interventions are evaluated. Participants, the main entry and exit conditions: All patients admitted to the emergency department of Masih daneshvari hospital with acute asthmatic attack in a period of twelve months, that fulfill the acceptance criteria have been enrolled. Inclusion criteria: history of asthma; aged between 18 and 65 years; Non-smoking; not pregnant; Lack of occupational asthma Exclusion criteria: critically ill patients requiring intensive care unit (life-threatening asthma); Infiltrates on chest x-ray; Hypercapnic respiratory failure Interventions: In addition to standard medical treatment, the control group received less than 10 liters per minute flow rate of oxygen. The intervention group also received standard medical treatment in addition to high flow oxygen dampened with over 10 liters per minute. Outcome variables: the Borg dyspnea score; Vital signs including respiratory rate; heart rate; blood pressure; temperatures; Spirometry; Peak flow meter; blood gases; blood cell counts; immunoglobulin E; Interleukin

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081727929N2**
Registration date: **2016-09-10, 1395/06/20**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-09-10, 1395/06/20

Registrant information

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Atefeh Fakharian
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National research institute of tuberculosis and lung diseases
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

From research found

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of High-Flow Oxygen Therapy on clinical and spirometry findings in Acute Exacerbation of Asthma

Public title

Effectiveness of High-Flow Oxygen Therapy on clinical and spirometry findings in Acute Exacerbation of Asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Admission criteria: a history of asthma; aged between 18 and 65 years; no history of smoking; no pregnancy; no history of occupational asthma Exclusion criteria: critically ill patients requiring intensive care unit (life-threatening asthma); infiltrates on chest x-ray ; Hypercapnic respiratory failure

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:

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 shahid beheshti university of medical sciences

Street address

7th Floor, Bldg No.2 shahid beheshti university of medical sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-08-09, 1395/05/19

Ethics committee reference number

IR.SBMU.NRITLD.REC.1395.230

Health conditions studied

1

Description of health condition studied

Acute asthma

ICD-10 code

J46

ICD-10 code description

Acute severe Asthma

Primary outcomes

1

Description

Respiratory rate

Timepoint

before, 2 and 24 hours after intervention

Method of measurement

Examination

2

Description

Dyspnea score

Timepoint

before, 2 and 24 hours after intervention

Method of measurement

Borg scale

3

Description

arterial oxygen saturation

Timepoint

before, 2 and 24 hours after intervention

Method of measurement

Arterial blood gas analysis

Secondary outcomes

1

Description

peak expiratory flow

Timepoint

before, 2 and 24 hours after intervention

Method of measurement

peak flowmeter

2

Description

forced expiratory volume in 1st second

Timepoint

before, 2 and 24 hours after intervention

Method of measurement

spirometry

Intervention groups

1

Description

Control group: oxygen therapy with low flow (less than 10 liters per minute)

Category

Treatment - Devices

2

Description
The intervention group received high-flow oxygen (between 10 to 50 liters per minute)
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
National research institute of tuberculosis and lung diseases
Full name of responsible person
Atefeh Fakharian
Street address
Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor in Research Affairs shahid Beheshti university of medical sciences
Full name of responsible person
Afshin Rezghi
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7th Floor, Bldg No.2 shahid Beheshti university of medical sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor in Research Affairs shahid Beheshti 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
National research institute of tuberculosis and lung diseases
Full name of responsible person
Sharareh Raeisi
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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