Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation of Non-invasive Positive Pressure Ventilation in patients with moderate to severe acute exacerbation of asthma

Protocol summary

Summary

(1) Objectives: Investigation of efficiency of noninvasive positive pressure ventilation in patients with moderate and severe asthma attacks referring to the emergency room of Masih Daneshvari Hospital (2) Design: Study population: all patients with moderate and severe asthma attacks referring to the emergency room of Masih Daneshvari Hospital, Sample Size: 34, blinding: double-blind, groups and randomization: random dividing of patients into intervention and control groups, study phase: clinical trial phase 2. (3) Setting and conduct: a) base line assessments in 34 patients, b) performing non-invasive ventilation in the intervention group with the inspiratory pressure equal to 12 cm H2O and expiratory pressure equal to 4 cm H2O via a face mask, c) using a same mask in the control group, d) comparing the results of two groups. (4) Participants including major eligibility criteria: Inclusion criteria: (1) Age between 18-75 years, (2) confirmed diagnosis of asthma. Exclusion criteria: (1) Chronic obstructive pulmonary disease, (2) patients inability to use mask (5) Intervention: in the intervention group: non-invasive ventilation using a face mask with an inspiratory pressure equal to 12 cm H2O and an expiratory pressure equal to 4 cm H2O for 120 minutes. In the control group: using a same mask without any pressure for 120 minutes. (6) Main outcome measures (primary and secondary outcome variables): primary outcome variable: forced expiatory volume in 1st second, secondary outcome variables: arterial PO2, arterial PCO2, blood pressure, heart rate, Dyspnea.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021427929N4**
Registration date: **2017-03-27, 1396/01/07**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-03-27, 1396/01/07

Registrant information

Name
Atefeh Fakharian
Name of organization / entity
National research institute of tuberculosis and lung diseases
Country
Iran (Islamic Republic of)
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+98 21 2712 2541
Email address
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti university of medical sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of Non-invasive Positive Pressure Ventilation in patients with moderate to severe acute exacerbation of asthma

Public title

Effectiveness of Non-invasive Ventilation in patients with

asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18-75 years; dyspnea; peak expiratory flow <200cc; respiratory rate >24/minute; confirmed diagnosis of asthma; receiving standard asthma treatment. Exclusion criteria: Chronic obstructive pulmonary disease; unstable vital signs such as systolic blood pressure <90 mmHg after liquid therapy; patient unwillingness to participate in the study; decrease in level of consciousness; acute myocardial infarction or ischemic heart failure; pH<7.10; unable to use mask; inability to clean airway secretions.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **34**

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

Shahid Beheshti University of Medical Sciences

Street address

7th Floor , 2nd SBUMS Bldg. ,Next to Ayatollah Taleghani Hospital, Evin

City

Tehran

Postal code

Approval date

2016-05-10, 1395/02/21

Ethics committee reference number

IR.SBMU.MSP.REC.1395.60

Health conditions studied

1

Description of health condition studied

asthma

ICD-10 code

J46

ICD-10 code description

Acute severe asthma

Primary outcomes

1

Description

Forced expiatory volume in 1st second

Timepoint

Before and after intervention

Method of measurement

spirometry

Secondary outcomes

1

Description

arterial PO2

Timepoint

Before and after intervention

Method of measurement

arterial blood gas

2

Description

arterial PCO2

Timepoint

Before and after intervention

Method of measurement

arterial blood gas

3

Description

Blood pressure

Timepoint

Before and after intervention

Method of measurement

Clinical counting

4

Description

Heart rate

Timepoint

Before and after intervention

Method of measurement

Clinical counting

5

Description

Dyspnea

Timepoint

Before and after intervention

Method of measurement

Dyspnea Borg Scale

Intervention groups

1

Description

In the intervention group: non-invasive ventilation is performed via a face mask with an inspiratory pressure equal to 12 cm H2O and an expiratory pressure equal to 4 cm H2O for 120 minutes. Non-invasive ventilation device configurations based on guidelines published by the Lung Association will be conducted in Europe and America.

Category

Treatment - Devices

2

Description

In the control group, a non-invasive device with a face mask without inspiratory and expiratory pressures is placed on the patients faces for 120 minutes.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Atefeh Fakharian

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 , Arabi Ave, Daneshjoo Blvd, Velenjak,

City

Tehran

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, 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

Dr. Atefeh Fakharian

Position

Pulmonologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Atefeh Fakharian

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Person responsible for updating data

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Full name of responsible person
Atefeh Fakharian

Position
Pulmonologist

Other areas of specialty/work

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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