

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Assessment and comparison of two standard protocols for management of asthma attack in patients admitted to Imam Khomeini and Golestan Hospitals emergency rooms in Ahwaz, Iran

Protocol summary

Study aim

Assessment and comparison of two standard protocols for management of asthma attack in patients admitted to Imam Khomeini and Golestan Hospitals emergency rooms in Ahwaz, Iran

Design

This study include 66 patients divided in two intervention and control groups; each group with 33 patient. It is a double blind study. Patients are coded in bases of table of random number, then are divided to two groups. Analyzer coding patients in basis of table of random numbers. Patients, research fellow and evaluator of events kept to be blind. This study is a phase 3 type clinical trial.

Settings and conduct

This is study will be done at Golestan and Imam Khomeini hospital of ahvaz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with clinical and para clinical approved asthma with clinical presentation of acute asthma attack and minimum age 18 years old and maximum 65 years old. Exclusion criteria: COPD, CHF, pnumonia, lung disease, nursing mothers, pregnancy, fever, administration of salbutamol in the last 6 hours.

Intervention groups

Intervention group: the intervention group were recorded at 0, 20, 40, 60 spirometric values of FEV1 and PEFR were measured and recorded. For each patient to record the values of FEV1 and PEFR, 3 times a spirometry performed and is considered the highest number. Immediately after spirometry, nebulize salbutamol dose (2.5 mg), as well as magnesium sulfate 2.5 CC Of 20 g / 100CC done. The control group were recorded at 0, 20, 40, 60 spirometric values of FEV1 and PEFR were measured and recorded. For each patient to record the values of FEV1 and PEFR, 3 times a spirometry performed and is considered the highest number.

Immediately after spirometry, nebulize salbutamol 2 / 5CC (2.5 mg), with 1.5 CC of saline in the control group will receive.

Main outcome variables

Clinical state; forced expiratory volume in first second; peak expiratory flow rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151103024853N3**

Registration date: **2018-07-15, 1397/04/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-15, 1397/04/24**

Update count: **0**

Registration date

2018-07-15, 1397/04/24

Registrant information

Name

Leila Kouti

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment and comparison of two standard protocols for management of asthma attack in patients admitted to Imam Khomeini and Golestan Hospitals emergency rooms in Ahwaz, Iran

Public title

Assessment and comparison of two standard protocols for management of asthma attack

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with clinical and para clinical approved asthma with clinical presentation of acute asthma attack Age: minimum 18 years old and maximum 65 years old

Exclusion criteria:

COPD CHF Pneumonia Lung disease Nursing mothers Fever Pregnancy Administration of salbutamol in the last 6 hours

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients to be coding in bases of table of random number, then divide to two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, research fellow and evaluator of events kept blind

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of ahvaz University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan blvd., Ahvaz

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Ahvaz

Province

Khuzestan

Postal code

61357-15794

Approval date

2017-12-05, 1396/09/14

Ethics committee reference number

IR.AJUMSA.REC.1396.817

Health conditions studied**1****Description of health condition studied**

Acute asthma attack

ICD-10 code

J45.901

ICD-10 code description

Unspecified asthma with (acute) exacerbation

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 Secend (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

Pulse Oximetry

Intervention groups

1

Description

Intervention group: the intervention group were recorded at 0, 20, 40, 60 spirometric values of FEV1 and PEFr were measured and recorded. For each patient to record the values of FEV1 and PEFr, 3 times a spirometry performed and is considered the highest number. Immediately after spirometry, nebulize salbutamol dose (2.5 mg), as well as magnesium sulfate 2.5 CC Of 20 g / 100CC done.

Category

Treatment - Drugs

2

Description

Control group: the control group were recorded at 0, 20, 40, 60 spirometric values of FEV1 and PEFr were measured and recorded. For each patient to record the values of FEV1 and PEFr, 3 times a spirometry performed and is considered the highest number. Immediately after spirometry, nebulize salbutamol 2 /

5CC (2.5 mg), with 1.5 CC of saline in the control group will receive.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

DR. leila kouti

Street address

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2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badavi

Street address

Ground floor, Deputy of research and technology developement, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Leila Kouti

Positionboard certified clinical pharmacist / Assistant
Professor**Latest degree**

Specialist

Other areas of specialty/work

Medical Pharmacy

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PositionBoard certified clinical pharmacist / Assistant
Professor**Latest degree**

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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PositionBoard certified clinical pharmacist / Assistant
Professor**Latest degree**

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available