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

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8379

Email address

kouti-l@ajums.ac.ir

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
City
Ahvaz
Province
Khouzestan
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
golestan,Ahvaz Golestan Hospital
City
ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3374 3001
Email
lkouti.pharmacotherapy@gmail.com

2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr . Leila Kouti
Street address
Imam Khomeini Hospital , 24 metri street, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3222 2818
Email
lkouti.pharmacotherapy@gmail.com

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.
City
ahvaz

Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3336 2414
Email
itc@ajums.ac.ir

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
Position
board certified clinical pharmacist / Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Ahvaz Faculty of Pharmacy, Golestan street, Ahvaz
City
ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8380
Email
lkouti.pharmacotherapy@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Leila Kouti
Position
Board certified clinical pharmacist / Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Ahvaz Faculty of Pharmacy, Golestan street, Ahvaz
City
ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8380
Email
lkouti.pharmacotherapy@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Leila Kouti
Position
Board certified clinical pharmacist / Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Ahvaz Faculty of Pharmacy, Golestan street, Ahvaz
City
ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8380
Email
lkouti.pharmacotherapy@gmail.com

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