

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effects of adding inhaled Aminophylline to the standard treatment of asthma in adults with acute severe asthma attack

Protocol summary

Summary

Adult patients older than 18 years old presenting to the emergency department of Imam Reza hospital with acute severe asthma attack 18 include in the study and they randomly assign to case and control group. For all the patients before the treatment, PEFR is measured by a handheld peak flow meter and respiratory rate, Pulse rate and O2 saturation are measured too and the patients will be asked to rate their severity of dyspnea based on a numeric rating scale from 1 to 10. The standard asthma treatment is given to two groups (The standard treatment includes 2.5 mg Salbutamol with 0.5mg Atrovent through nebulizer each 20 min until three dose plus 300mg Hydrocortison). In the case group, after second dose of Salbutamol, 250mg Aminophyllin with Concentration 25ml/mg is prescribed through nebulizer and for the control group we give Distilled water is through nebulizer instead. After 20 min for both groups the third dose of salbutamol and atrovent is given (continue of the standard treatment). So both groups are treated by 3 dose of nebulized salbutamol and atrovent every 20 min and after the second dose of salbutamol, the case group are administered nebulized aminophylline while the control group receive distilled water as placebo. For all the patients at the end of the first hour of treatment, PEFR is measured by a handheld peak flow meter and respiratory rate, Pulse rate and O2 saturation are measured too. The patients will be asked to rate their severity of dyspnea again. It is also documented if the patient became intubated during the 6 hours after treatment and if he/she is admitted to the hospital. Improving in PEFR and hospital admission are considered as primary outcomes and intubation, improving in subjective dyspnea, Pulse oximetry and respiratory rate, are considered as secondary outcome. The patients are compared in regard to these outcomes to see if adding nebulized aminophylline to the standard treatment would be able to improve each of these outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082329494N1**

Registration date: **2017-03-01, 1395/12/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-01, 1395/12/11

Registrant information

Name

Bahare Mirzajani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 915 509 0914

Email address

mirzajani931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effects of adding inhaled Aminophylline to the standard treatment of asthma in adults with acute severe asthma attack

Public title

Effects of inhaled Aminophylline for treatment of asthma attack

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient older than 18 years old presented by severe asthma attack to Exclusion criteria: not consent for participating in the study, uncooperative in physical exam, nebulizer, aminophylline contra-indications, pregnancy, present or history of tachy-disrhythm , drug history of theophylline use.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Ghorieshi Bulding. Daneshgah Street, Mashhad

City

Mashhad

Postal code

Approval date

2016-10-19, 1395/07/28

Ethics committee reference number

IR.MUMS.sm.REC.1395.290

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J46

ICD-10 code description

Status asthmaticus

Primary outcomes

1

Description

Admit

Timepoint

6 hours later

Method of measurement

Admit- Non Admit

2

Description

PEFR

Timepoint

Before Treatment- one hour later treatment

Method of measurement

Utilizing PEFR

Secondary outcomes

1

Description

improving in subjective dyspnea

Timepoint

Before treatment- One hour later treatment

Method of measurement

NUMERIC RATING 10 Criteria

2

Description

Respiratory rate

Timepoint

Before and one hour later treatment

Method of measurement

Counting

3

Description

Pulse Oximetry

Timepoint

Before and one hour later treatment

Method of measurement

Utilizing Pulse Oximetry

Intervention groups

1

Description

Administration aminophylline through nebulizer in Intervention Group

Category

Treatment - Drugs

2

Description

administration distill water through nebulizer in control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

emamrezahospital

Full name of responsible person

bahareh mirzajani bajestani

Street address

emergency department edalatian

City

mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

mashhad University of Medical Sciences

Full name of responsible person

Dr. tafaghodi

Street address

mashhad research dept, Ghorieshi Building, Daneshgah Street

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Bahare Mirzajani Bajestani

Position

Resident of Emergency Medicine

Other areas of specialty/work

Street address

Emam Reza Hospital- Emergency department Edalatian

City

Mashhad

Postal code

Phone

+98 518525312

Fax

Email

mirzajani931@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Elham Pishbin

Position

Assistant Professor of Emergency Medicine

Other areas of specialty/work

Street address

Emam Reza hospital- Emergency department Edalatian

City

Mashhad

Postal code

Phone

+98 51 3852 5312

Fax

Email

pishbine@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Bahare Mirzajani Bajestani

Position

resident of Emergency Medicine

Other areas of specialty/work

Street address

No.13, No.15 Sharif Avenue, No.59 Vakil Abad BLV

City
Mashhad
Postal code
Phone
00
Fax
Email
Mirzajanib931@mums.ac.ir
Web page address

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