

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of clinical and peak flowmetry of nebulized Ketamin in acute asthma attack

Protocol summary

Summary

The method of study is explained to all patients, and patient who do not express their consent in writing are not studied. If there are no prohibition factors for the patients based on the inclusion criteria and if there are no exclusion criteria, the sample size of the patients is randomly divided into two groups of case(120 member) and control(120 member). according to the severity of the asthma attack, they will undergo standard asthma treatment according to the reference book protocols . Patients with severe and severe moderate are treated with 2.5 mg inhaled albuterol and 0.5 mg inhalation ipratropium 0.5 mg with a 20 minute interval. Patients with severe onset of severe asthma received 5 mg inhalable albuterol and 0.5 mg inhalation epirubanol At intervals of 20 minutes, three non-vial doses. and 50 mg oral prednisolone are given. In the experimental group, 1mg / kg of ketamine was inhaled in addition to the standard treatment mentioned in 1 doses of 0, minute, and measured PEFr and FEV1 in all patients at 0, 20, 40, 60, and 90 minutes after the intervention, . Meanwhile, in the 60th minute, the clinical status of patients (according to Rosen 2014) based on clinical symptoms, the state of consciousness, speaking,HR , RR , , paradoxical rat, the use of accessory respiratory muscles, and wheezing are reassessed and evaluated. Clinical parameters, PEFr and FEV1 are measured before and after 0, 20, 40, 60, and 90 minutes. Respiratory rate, heart rate, blood pressure and oxygen saturation are also recorded. Finally, the difference between the two parameters is the two groups receiving the treatment and statistical analysis

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017063015446N10**

Registration date: **2017-07-11, 1396/04/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-11, 1396/04/20

Registrant information

Name

Hassan Motamed

Name of organization / entity

Emergency Department , Ahvaz Jundishapour University of Medical Sciences , Ahvaz , Iran

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3079

Email address

motamed-h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University Of Medical Science

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-11-25, 1396/09/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clinical and peak flowmetry of nebulized Ketamin in acute asthma attack

Public title

Evaluation of clinical and peak flowmetry of nebulized Ketamin in acute asthma attack

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: At least 18 years of age and up to 65 years old, patients with complaints of acute shortness of breath have been referred to the emergency department and According to the early symptoms, asthma was diagnosed (Triad shortness of breath;diffusion wheezing and cough) Exclusion criteria: Patients with lungs disorder and asthmatic manifestations such as ILD ... Smokers with more than 10packs per year of smoking, history of chronic bronchitis, acute medical problem, coronary artery disease, cardiac arrhythmia, high intracranial pressure, women Pregnant and nebolizer beta-agonist treatment for the past 6 hours, and mild and severe asthma attack are excluded

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **240**

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

Ahvaz Jundishapor University of Medicial Sciences

Street address

Ahvaz Jundishapor University of Medicial Sciences, Golestan st.

City

Ahvaz

Postal code

Approval date

2017-06-16, 1396/03/26

Ethics committee reference number

IR.AGUMS.REC.1396.235

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

FEV1

Timepoint

At 0,20, 40, 60, 90,minutes Since the beginning of the intervention

Method of measurement

Litre, by spirometry

2

Description

Peak Expiratory Flow Rate (PEFR)

Timepoint

At 0,20, 40, 60, 90,minutes Since the beginning of the intervention

Method of measurement

Litre, by spirometry

Secondary outcomes

1

Description

Respiratory rate

Timepoint

Minutes 0, 20, 40, 60and 90 since the beginning of the intervention

Method of measurement

Counting of respiration in one minute

2

Description

Pulse rate

Timepoint

Minutes 0, 20, 40, 60and 90 since the beginning of the intervention

Method of measurement

Counting of pulse in one minute

3

Description

Blood pressure

Timepoint

Minutes 0, 20, 40, 60and 90 since the beginning of the intervention

Method of measurement

mmHg, by sphygmomanometer

4**Description**

blood oxygen saturation levels (SpO2)

Timepoint

Minutes 0, 20, 40, 60 and 90 since the beginning of the intervention

Method of measurement

Percentage, by pulse oximeter

Intervention groups**1****Description**

In the case group, 1 mg / kg of ketamine is inhaled in 1 dose at 0 minutes

Category

Treatment - Drugs

2**Description**

in two group, 2.5 mg inhaled albuterol. In 3 doses with a 20 minute interval

Category

Treatment - Drugs

3**Description**

In both intervention and control groups. Ipratropium 0.5 mg inhaler with a 20 minute interval in three doses

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Khomeini and Golestan hospitals in Ahvaz

Full name of responsible person

Dr. Hasan Motamed

Street address**City**

Ahvaz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz Jundishapur University Of Medical Science

Full name of responsible person

Dr Hassan Motamed

Street address

Department of emergency medicine, Golestan Hospital, Ahvaz, Iran

City

ahvaz

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

Yes

Title of funding source

Ahvaz Jundishapur University Of Medical Science

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**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Hassan Motamed

Position

Emergency medicine assistant professor

Other areas of specialty/work**Street address**

Golestan hospital, Golestan st.

City

Ahvaz

Postal code**Phone**

+98 61 3374 3079

Fax**Email**

motamed-h@ajums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Hassan Motamed

Position

Emergency medicine assistant professor

Other areas of specialty/work**Street address**

Golestan hospital, Golestan st.

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Fax

Email

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Web page address

+98 61 3374 3079

Fax

Email

motamed.h@ajums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapor University of Medical Sciences

Full name of responsible person

Dr. Hassan Motamed

Position

Emergency medicine assistant professor

Other areas of specialty/work

Street address

Golestan hospital, Golestan St.

City

Ahvaz

Postal code

Phone

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