Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of ketamine nebulizer with magnesium sulfate in the treatment of patients with corticosteroid-resistant asthma referred to the emergency department

Protocol summary

Study aim

1. Determine the rate of improvement of PEFR 2. Determining the need for hospitalization

Design

α = 0.05 β = 0.2 ==.35 people in each group This study is a double-blind Block Randomization method and software will be divided into two groups.

Settings and conduct

Environment: Emergency Department of Shahid Rajaei Medical Center, Karaj. Society: Patients with corticosteroid-resistant asthma attack. Two-blind. Infusion in acute attack resistant to corticosteroid therapy using peak flowmetry all in one treatment session and measurement of PEFR, V / S before and 30 and 60 minutes of drug infusion with warning signs and possible side effects of the drug to the patient and readiness For necessary actions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age over 18 years old under 65 years - Corticosteroid resistant asthma attack - No history of allergy to ketamine or sulfamide Exclusion criteria: - Dissatisfaction to participate in the study - Age less than 18 years - More age From 65 years - Weight less than 40 kg - Drug or alcohol poisoning - Active psychiatric illness. History of ketamine allergy

Intervention groups

Intervention group: and patients treated with nebulizerctamine (0.3-0.1 mg / kg) from the target population

Main outcome variables

Comparison of the effect of ketamine nebulizer with magnesium sulfate in the treatment of patients with corticosteroid-resistant asthma attack 1. Determine the rate of improvement of PEFR 2. Determining the need for hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200914048715N1**
Registration date: **2020-09-20, 1399/06/30**
Registration timing: **prospective**

Last update: **2020-09-20, 1399/06/30**
Update count: **0**

Registration date

2020-09-20, 1399/06/30

Registrant information

Name

Kimia Farshadfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3421 4275

Email address

kfarshadfar1995@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-05, 1399/08/15

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of ketamine nebulizer with magnesium sulfate in the treatment of patients with corticosteroid-resistant asthma referred to the emergency department

Public title
Comparison of the effect of ketamine and magnesium sulfate on acute asthma attack

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age<65 age<>18 Corticosteroid-resistant asthma attack No history of allergy to ketamine or sulfamide

Exclusion criteria:
Dissatisfaction with participating in the study age<18 age>65 weight>40 Drug or alcohol poisoning Active psychiatric illness History of ketamine allergy

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
People will be randomly divided into two groups. This study is such that patients who are candidates for inclusion in the study, after examination in terms of inclusion and exclusion criteria and obtaining informed consent using Block Randomization and software will be divided into two groups and patients in the first group treated with nebulizers. (0.3-0.1 mg / kg) and the second group will be treated with magnesium sulfate infusion (2 gr (within 20 minutes).

Blinding (investigator's opinion)
Double blinded

Blinding description
This study was double-blind, so that the patient and the researcher were unaware of the status of the two groups assigned to the study. The researcher, who performs clinical and diagnostic measurements, was not aware of the status of individuals, and the statistical consultant was unaware of the allocation of individuals to study groups. Only one observer was aware of the allocation of groups. There will be two intervention and control groups, with standard treatment for both acute asthma attacks.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics commitee of Alborz University of Medical Sciences

Street address
Karaj - 45 meters from Golshahr - Saffarian Alley - Deputy of Research and Technology

City
karaj

Province
Alborz

Postal code
3198764653

Approval date
2020-05-30, 1399/03/10

Ethics committee reference number
IR.ABZUMS.REC.1399.080

Health conditions studied

1

Description of health condition studied
asthma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Type of treatment - Hospitalization requirement - Acute refractory asthma attack - PEFR

Timepoint
0-30-60 MIN

Method of measurement
Ketamine protocol - number of patients admitted - peak flowmetry

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

Intervention groups

1

Description
Intervention group: and patients will be treated with nebulizerctamine (0.3-0.1 mg / kg). Before and 30 and 60 minutes after treatment with ketamine nebulizer, PEFR was measured by peak flowmeter in the minutes before and 30 minutes and 60 minutes after treatment with vital signs, Spo2 and recorded in a questionnaire sheet and comparison of two methods by soft Analysis tools will be performed. Control group: Patients who are included in the study according to the inclusion criteria will be treated with magnesium sulfate infusion (2 gr) for 20 minutes. Before, 30 and 60 minutes after magnesium sulfate treatment, PEFR With peak flowmetry in the minutes before, 30 minutes and 60 minutes after treatment with vital signs, Spo2 will be measured and recorded in the questionnaire sheet and the comparison of the two methods will be done through analysis software.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emergency of Shahid Rajaei Medical Training Center in Karaj

Full name of responsible person
Kimia Farshadfar

Street address
Karaj, Hesarak, Shahid Rajaei St., Shahid Rajaei Educational and Medical Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
-

Full name of responsible person
-

Street address
-

City
-

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Postal code
-

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
-

Proportion provided by this source
1

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
mehdi rezari kojani

Position
Emergency medicine specialist

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be published after making it unrecognizable
When the data will become available and for how long
Starting from 1/4/1400
To whom data/document is available
University researchers
Under which criteria data/document could be used
In order to use in similar articles
From where data/document is obtainable
1.DR Mehdi Rezaei Kojani 2.Kimia Farshadfar
What processes are involved for a request to access data/document
Apply by e-mail first. After acceptance, access is possible by sending your official document and within about a month.
Comments