

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

$\alpha = 0.05$   $\beta = 0.2$   $n = 35$  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 committee 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

#### City

karaj

#### Province

Alborz

#### Postal code

3197635141

#### Phone

+98 26 3457 0030

#### Email

kfarshadfar1995@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

-

#### Full name of responsible person

-

#### Street address

-

#### City

-

#### Province

Alborz

#### Postal code

-

#### Phone

+98 26 3477 7777

#### Email

KFARSHADFAR1995@GMAIL.COM

#### 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

#### Street address

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#### City

karaj

#### Province

Alborz

#### Postal code

3197635141

#### Phone

+98 26 3457 0030

#### Email

rezaei.mehdi.md@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Karaj University of Medical Sciences

#### Full name of responsible person

mehdi rezaei kojani

**Position**

Emergency medicine specialist

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Specialist

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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**