

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Study of the effect of intravenous magnesium sulfate on clinical performance as a complementary therapy of the patients with COPD in the emergency department

#### Protocol summary

##### Study aim

This study want to determine the effect of intravenous magnesium sulfate in controlling the acute attack caused by chronic obstructive pulmonary disease (COPD) in patients referred to the emergency department of Imam Khomeini Hospital during a six-hour period.

##### Design

Randomized, double blind, controlled with placebo, single-centered, phase 3 of trial

##### Settings and conduct

Patients with chronic pulmonary obstruction with acute attack are examined at the time of admission, 45 minutes and 6 hours after intervention of primary outcomes and secondary outcomes, including respiratory rate and blood pressure in the emergency department of Imam Khomeini Hospital in Sari. Moreover, the standard treatment of the acute attack starts with intervention. Patients will not be informed about which group they are. Moreover, the pharmacist of the study will code the drugs (codes A, B) without the author's knowledge.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who refer to the emergency department for chronic obstructive pulmonary disease caused by smoking Non inclusion criteria: Patients who have the need for intubation; Patients who have a history of heart disease; patients who have a low level of consciousness; patients who received intravenous magnesium sulfate within the last 24 hours

##### Intervention groups

Interventional group: Magnesium sulfate 2% made by Obeidi pharmaceutical company is mixed with 200 ml normal saline and is administered using the peripheral vein through slow intravenous infusion within 20 minutes. Control group: Normal saline 0.9% (Obeidi factory) is given 100 cc once, under slow using the peripheral vein through slow intravenous infusion.

##### Main outcome variables

Number of breaths

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150315021480N8**

Registration date: **2018-05-09, 1397/02/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-05-09, 1397/02/19**

Update count: **0**

##### Registration date

2018-05-09, 1397/02/19

##### Registrant information

##### Name

Fatemeh Jahanian

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3336 1700

##### Email address

fjahanian@mazums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

##### Expected recruitment start date

2017-10-23, 1396/08/01

##### Expected recruitment end date

2018-09-23, 1397/07/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Study of the effect of intravenous magnesium sulfate on clinical performance as a complementary therapy of the patients with COPD in the emergency department

**Public title**  
The effect of intravenous magnesium sulfate as a complementary therapy to COPD

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All patients with chronic pulmonary obstruction with moderate severity.

**Exclusion criteria:**

Patients who have the need for intubation. Patients who have a history of heart disease Patients who have a low level of consciousness Patients who received intravenous magnesium sulfate within the last 24 hours

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are divided to two groups using simple randomization . In this way, we place each patient to toss up a coin head and tail in the intervention or control group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients will not be informed of the type of the group they will be. Moreover, the pharmacist of the study will code the drugs (codes A, B) without the author's knowledge. Thus, the nurse and distributor will also be unaware of the name of the drug received.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

In this study, the randomization of random number table was used.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Mazandaran University of Medical Sciences

**Street address**

Vice chancellor for research, Mazandaran University of Medical Sciences, Moalem Square, Sari, Iran

**City**

Sari

**Province**

Mazandaran

**Postal code**

4813656254

**Approval date**

2017-08-18, 1396/05/27

**Ethics committee reference number**

IR.MAZUMS.IMAMHOSPITAL.REC.1396.2761

## Health conditions studied

### 1

**Description of health condition studied**

Chronic obstructive pulmonary disease

**ICD-10 code**

J44

**ICD-10 code description**

J44

## Primary outcomes

### 1

**Description**

Number of breaths

**Timepoint**

Counting the number of breaths at the beginning of the study (before the intervention) and 45 minutes and 6 hours after starting magnesium sulfate

**Method of measurement**

We count the breath per one minute

## Secondary outcomes

### 1

**Description**

blood pressure

**Timepoint**

before intervention and 45 minutes and 6 hours after intervention

**Method of measurement**

We get blood pressure using a manometer portable .

## Intervention groups

### 1

#### Description

Intervention group: Magnesium sulfate (2%) Obiidi pharmaceutical company is mixed with 200 ml of normal saline and is given intravenous infusion intravenously in 20 minutes

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Normal saline 0.9% (Obeidi factory) is given 100 cc once, under slow given intravenous infusion intravenously

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Khomeini hospital of Sari

##### Full name of responsible person

Sepideh Amirifar

##### Street address

Emergency Medicine Department, Imam Khomeini Hospital, Amir Mazandarani Street, Sari, Iran

##### City

Sari

##### Province

Mazandaran

##### Postal code

4813656148

##### Phone

+98 11 3322 1755

##### Email

bnf.nr70@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Sciences

##### Full name of responsible person

Ahmad Ali Enayati

##### Street address

Mazandaran University Of Medical Sciences, The beginning of the highway Valiasser, Joybar Three-way, Imam (AS) square

##### City

Sari

##### Province

Mazandaran

##### Postal code

4813656526

##### Email

BNF.nr70@gmail.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice chancellor for research of Mazandaran 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

Mazandaran University of Medical Sciences

##### Full name of responsible person

Sepideh Amirifar

##### Position

Residency Of Emergency Medicine

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Emergency Medicine

##### Street address

Emergency Medicine Department, Imam Khomeini Hospital, Amir Mazandarani Street, Sari, Iran

##### City

Sari

##### Province

Mazandaran

##### Postal code

4813656148

##### Phone

+91 11555084

##### Fax

##### Email

sepidehamirifard@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Fatemeh Jahanian

##### Position

Emergency Medicine Specialist  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
**Street address**  
Emergency Medicine Department, Imam Khomeini  
Hospital, Amir Mazandarani Street, Sari, Iran  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4813656148  
**Phone**  
00  
**Fax**  
**Email**  
sepidehamirifard@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Sepideh Amirifard  
**Position**  
Residency of Emergency Medicine  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
**Street address**  
Emergency Medicine Department, Imam Khomeini  
Hospital, Amir Mazandarani Street, Sari, Iran  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4813656148  
**Phone**

+91 11555084

**Fax**  
**Email**  
sepidehamirifard@gmail.com  
**Web page address**

## 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

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

All data, such as information on the main outcome will be released after the publication of the article.

### When the data will become available and for how long

April 2018 to May 2018

### To whom data/document is available

Available only to researchers in academic and scientific institutions

### Under which criteria data/document could be used

There is no limitation.

### From where data/document is obtainable

sepideh amirifard. sepidehamirifard@gmail.com

### What processes are involved for a request to access data/document

Send your request to the respondent's email. If the intended article is published, we will share the data with other researchers, but we will not disclose the data before the publication process

### Comments