

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)

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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

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Jahanian

Position

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Person responsible for updating data

Contact

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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