Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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
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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
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Position

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Latest degree

Specialist

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Latest degree

Medical doctor

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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