

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

comparison of effects of nebulised Furosemide, oxygen and placebo in patients with acute dyspnea transmitted to hospitals by EMS

Protocol summary

Study aim

comparison of effects of nebulised Furosemide, oxygen and placebo in patients with acute dyspnea transmitted to hospitals by EMS

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 300 patients. In order to randomize, the block randomization method will be used.

Settings and conduct

In this study, All patients with acute dyspnea transferred to hospitals by emergency will be enrolled. Patients will be randomly divided into 3 groups based on Blocks with size 12. The sample size for each study group is 100. A total of 300 patients will be examined. Patients and data analyzer will be blind.

Participants/Inclusion and exclusion criteria

All patients with acute dyspnea transferred to hospitals by emergency will be enrolled. Inclusion criteria: Patient transfer by pre-hospital emergency, patients over 18 years, . Exclusion criteria: patients over 75 years, Patients require mechanical ventilation, Loss of consciousness, Accompanied by another disease that requires treatment in the first 10 minutes of treatment with digoxin, beta-blocker, beta-agonist and calcium blocker, Need another inhalation treatment in the first 10 minutes, Need non-invasive positive pressure ventilation

Intervention groups

Intervention group 1: In addition to routine treatment, 40 mg of inhaled furosemide will be given as a nebulizer at the scene. Intervention group 2: In addition to routine treatment, oxygen will be administered at the scene with a mechanical nebulizer. Control group: In addition to routine treatment, 10 cc of normal saline will be prescribed as a placebo at the scene.

Main outcome variables

Acute dyspnea; Percentage of oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151003024317N12**

Registration date: **2020-11-10, 1399/08/20**

Registration timing: **prospective**

Last update: **2020-11-10, 1399/08/20**

Update count: **0**

Registration date

2020-11-10, 1399/08/20

Registrant information

Name

Mahdi Rezai

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8868 6772

Email address

rezaei.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of effects of nebulised Furosemide, oxygen and placebo in patients with acute dyspnea transmitted to hospitals by EMS

Public title

Evaluation of the effect of nebulised Furosemide on acute dyspnea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute dyspnea Patient transfer by pre-hospital emergency patients over 18 years old

Exclusion criteria:

patients over 75 years old Patients require mechanical ventilation Loss of consciousness Accompanied by another disease that requires treatment in the first 10 minutes of treatment with digoxin, beta-blocker, beta-agonist and calcium blocker Need another inhalation treatment in the first 10 minutes Need non-invasive positive pressure ventilation

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to three groups by using a random number table. In order to randomize, a random block method will be used. For this purpose, we formed blocks of size 12. In each block, 4 individuals will be in intervention group 1, 4 individuals will be in intervention group 2 and 4 will be in control group. A total of 25 blocks will be considered for the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Clinical caregivers and patients will be unaware and blind to the type of treatment. Similar serums were used for concealment, without drug name label and only with code. Patients will be aware that they will be randomly assigned to one of three treatment groups, but will not know which treatment will be offered in that group. Patients will be placed in one of three groups using a random number table. The clinician also knows that patients will be treated in three different ways, but will not know which method will be used for each patient. The data collector, analyst, outcome assessor, and data safety and monitoring committee will collect and analyze the information based on groups 1, 2, and 3, and will not be aware of the type of treatment provided in the

groups. They will be kept blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-10-07, 1399/07/16

Ethics committee reference number

IR.IUMS.REC.1399.632

Health conditions studied

1

Description of health condition studied

Acute dyspnea

ICD-10 code

R06.0

ICD-10 code description

Dyspnea

Primary outcomes

1

Description

Acute dyspnea

Timepoint

Before intervention, thirty minutes after intervention

Method of measurement

Shortness of breath chart

2

Description

Percentage of oxygen saturation

Timepoint

Before intervention, thirty minutes after intervention

Method of measurement

Percentage of oxygen saturation

Secondary outcomes

1

Description

Heart rate

Timepoint

Before intervention, thirty minutes after intervention

Method of measurement

Based on the information recorded in patient's record

2

Description

Number of breaths

Timepoint

Before intervention, thirty minutes after intervention

Method of measurement

Based on the information recorded in patient's record

Intervention groups

1

Description

Intervention group 1: In addition to routine treatment, 40 mg of inhaled furosemide will be given as a nebulizer at the scene.

Category

Treatment - Drugs

2

Description

Intervention group 2: In addition to routine treatment, oxygen will be prescribed at the scene with a mechanical nebulizer.

Category

Treatment - Drugs

3

Description

Control group: In addition to routine treatment, 10 cc of normal saline will be prescribed as a placebo at the scene.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul Akram hospital

Full name of responsible person

Babak Mahshidfar

Street address

Emergency department, Hazrate Rasool hospital,
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2

Recruitment center

Name of recruitment center

Firouzgar hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Iran 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

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Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Babak Mahshidfar

Position

Assistant Professor of Emergency Medicine

Latest degree

Specialist

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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Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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City

Tehran

Province

Tehran

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available