Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of furosemide inhalation versus placebo in patients with acute cardiogenic pulmonary edema

Protocol summary

Summary

The study is aimed to evaluate the effect of 40 milligram of inhaled Furosemide versus placebo in patients with early diagnosis of cardiogenic pulmonary edema. The study is a randomized controlled clinical trial that will be conducted in Hazrat-e Rasool-e-Akhram and Firoozghar Hospitals affiliated by Iran University of Medical Sciences during the first half of 2018. This study will be double-blind in which patients and doctors assessing the clinical status of patients will not be aware of the intervention. All patients with primary diagnosis of acute pulmonary involvement will be included in the study, and the exclusion criteria are history of susceptibility to sulfa-containing drugs, inability of the patient to cooperate; unstable hemodynamics; requiring mechanical ventilation; decreased consciousness. 120 patients will be assigned to the treatment group (60) and control (60) using the blocked randomized method. In the treatment group, 40 milligram of Furosemide is inhaled in addition to routine treatment. In control group, Normal Saline will be prescribed as a placebo in addition to routine treatment. The intervention time is within the first 10 minutes of treatment. Patients in both groups will be evaluated at baseline and 10 minutes after intervention in terms of oxygen saturation, respiration rate, heart rate, arterial blood gases, dyspnea based on visual analog scale (VAS), Crackles and Wheezing and decreased lung sounds.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101436753N1**
Registration date: **2017-11-18, 1396/08/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-18, 1396/08/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-09-28, 1396/07/06

Expected recruitment end date

2018-03-31, 1397/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of furosemide inhalation versus placebo in patients with acute cardiogenic pulmonary edema

Public title

Compare effect of furosemide inhalation versus placebo in patients with acute cardiogenic pulmonary edema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All the patients with acute cardiogenic edema will be included in the study. Exclusion criteria: not willing to participate in the study, history of susceptibility to sulfa drugs, unstable hemodynamics; requiring mechanical ventilation; decreased consciousness, accompany with another illness requiring treatment in the first 10 minutes of treatment with digoxin, beta blocker, beta-agonist and calcium; need to have another inhaling treatment in the first 10 minutes and need to have non-invasive ventilation.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.IUMS.REC.1365.9411307025

Health conditions studied

1

Description of health condition studied

Acute pulmonary oedema

ICD-10 code

I50.1

ICD-10 code description

Left ventricular failure

Primary outcomes

1

Description

Oxygen saturation

Timepoint

Baseline and 10 minutes after intervention

Method of measurement

Pulse oximeter

2

Description

Respiratory rate

Timepoint

Baseline and 10 minutes after intervention

Method of measurement

Number of breaths per minute

3

Description

Heart rate

Timepoint

Baseline and 10 minutes after intervention

Method of measurement

Heart beats at per minute

4

Description

Arterial blood gases

Timepoint

Baseline and 10 minutes after intervention

Method of measurement

Arterial blood gases test

5

Description

Dyspnea Severity

Timepoint

Baseline and 10 minutes after intervention

Method of measurement

MMRC Dyspnea Severity Scale

Secondary outcomes

1

Description

Crackles

Timepoint

Baseline and 10 minutes after intervention

Method of measurement

Stethoscope

2

Description
Wheezing
Timepoint
Baseline and 10 minutes after intervention
Method of measurement
Stethoscope

Intervention groups

1

Description
Control group: Normal Saline as a placebo will be prescribed through nebulizer in addition to routine treatment at the first 10 minutes.
Category
Treatment - Drugs

2

Description
Intervention group: 40 milligram of Furosemide is inhaled through nebulizer in addition to routine treatment at the first 10 minutes
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul-e Akram Hospital
Full name of responsible person
Amir Sadegh Alimardani
Street address
Niyayesh St, Sattar Khan St
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Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Kazem Malakouti
Street address
Iran University of Medical Sciences, Hemmat Highway
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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, Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
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Babak Mahshidfar
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty