

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Name

Babak Mahshidfar

Name of organization / entity

Iran University of Medical Sciences

Country

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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

City

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

City

Tehran

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

Full name of responsible person

Babak Mahshidfar

Position

Emergency Medicine Specialist

Other areas of specialty/work

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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