Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparison of effects of nebulised Frusemide and placebi in patients with acute dyspnea transmited by EMS

Protocol summary

Study aim
comparison of effects of nebulised Frusemide and placebi in patients with acute dyspnea transmited by EMS
Design
randomized, parallel group with blinded,
Settings and conduct
in Tehran EMS, in ambulances of Tehran
Participants/Inclusion and exclusion criteria
All the patients with acute dyspnea 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.
Intervention groups
all patients 18 to 75 years old devided in 3 groups; for first group nebulized Furosemide, second group nebulized placebo and for third group nothing nebulized.
Main outcome variables
pulse rate, respiratory rate, visual analogue score, O2 saturation, need to mechanical ventilation in hospital

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171014036753N2**
Registration date: **2019-01-08, 1397/10/18**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-08, 1397/10/18**
Update count: **0**
Registration date
2019-01-08, 1397/10/18

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-11-26, 1397/09/05
Expected recruitment end date
2019-03-20, 1397/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
comparison of effects of nebulised Frusemide and placebi in patients with acute dyspnea transmited by EMS

Public title
comparison of effects of nebulised Frusemide and placebi in patients with acute dyspnea transmited by EMS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
all patient between 18 to 75 years old with dyspnea who transmitted to hospitals by EMS

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
table of random numbures

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and EMS staff

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

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2018-05-09, 1397/02/19

Ethics committee reference number
IR.IUMS.FMD.REC1396.9411307033

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
Oxygen saturation

Timepoint
baseline until arrive to hospital

Method of measurement
Pulse oximeter

2

Description
MMRC Dyspnea Severity Scale

Timepoint
baseline until arrive to hospital

Method of measurement
Visual Analouge Scale

Secondary outcomes

1

Description
severity of dyspnea

Timepoint
baseline until to arrive to hospital

Method of measurement
visual analogue scale by EMS staff

Intervention groups

1

Description
Intervention group: 40 milligram of Furosemide is inhaled through nebulizer in addition to routine treatment in ambulances

Category
Treatment - Drugs

2

Description
Control group: Normal Saline as a placebo will be prescribed through nebulizer in addition to routine treatment in ambulances

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
EMS in Thran
Full name of responsible person
Mojdeh Mirkheshti
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Person responsible for general inquiries

Contact

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Associate professor
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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
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