

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

2019-01-08, 1397/10/18

#### 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

#### Registrant information

##### Name

Babak Mahshidfar

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6653 9255

##### Email address

mahshidfar.b@iums.ac.ir

#### 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 numbers

**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 Analogue 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

**Street address**

No 86, Khalilabadi st, Sattari Expway Tehran

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14492614535

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research@tehran115.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Kazem Malakouti

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Iran University of Medical Sciences, Hemmat Highway

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research@iums.ac.ir

**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

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Babak Mahshidfar

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Mojdeh Mirkheshti

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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