

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effect of Dizepam on control of acute attack of dyspnea in patients referring to the emergency department

Protocol summary

Study aim

Evaluation of Dizepam on control of acute attack of dyspnea in patients referring to the emergency department

Design

This study is clinical trial and double blind. 374 patients with acute attack of dyspnea to referring emergency department of Valiasr Hospital and Amiral-Momenin Arak Hospital will enter this study. We will divide patients in 2 groups by simple randomization. Groups are parallel.

Settings and conduct

374 patients with acute attack of dyspnea to referring emergency department of Valiasr Hospital and Amiral-Momenin Arak Hospital will enter this study. Outcome assessor and analyzer don't aware from grouping. We check respiratory distress, level of consciousness and dyspnea.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with dyspnea, age older than 18 years, P_{CO_2} less than 0.85, level of consciousness is higher than 11. Exclusion criteria: failure to dissatisfaction and follow up

Intervention groups

Control group: Depending on the severity of the dyspnea, they are treated as follows: Use of spray: Salbutamol; Atrovent, injectable corticosteroid use; nebulizer treatment, oxygen therapy, use of injectable beta-agonist. We give diuretic and nitroglycerine serum in patients with symptoms of pulmonary edema. Intervention group: In addition to the routine treatment in the control group, they are treated with 10 milligram of Diazepam (IV injection within a 3 to 4 minute interval).

Main outcome variables

Respiratory distress, level of consciousness, dyspnea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N122**

Registration date: **2019-09-30, 1398/07/08**

Registration timing: **retrospective**

Last update: **2019-09-30, 1398/07/08**

Update count: **0**

Registration date

2019-09-30, 1398/07/08

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2019-08-06, 1398/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Dizepam on control of acute attack of dyspnea in patients referring to the emergency department

Public title

Effect of Dizepam on control of dyspnea in patients referring to emergency department

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with dyspnea Age older than 18 years Pco2 less than 0.85 level of consciousness is higher than 11

Exclusion criteria:

Dissatisfaction

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **374**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random number table in division of groups in two groups A and B
Randomization method: Simple randomization. Random unit: Individual. How to build sequences: First, we will set the framework for our statistical society. We will start from a table point in a row or column. Given the type of code in the row, we will choose the same number of digits. After that, the numbers control the path. We will notice smaller numbers of the statistical community. We will have to continue this work so that the number of samples is complete. Even numbers will use for intervention group and odd numbers will use for the control group. Allocation concealment: Numbered drug containers

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor. In order to blind the diazepam and distilled water in two groups, the syringe covered with white paper on which they are written A and B. Syringes are provided to the resident.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Arak University Of Medical Sciences

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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Province

Markazi

Postal code

3848176941

Approval date

2018-03-04, 1396/12/13

Ethics committee reference number

IR.ARAKMU.REC.1396.310

Health conditions studied

1

Description of health condition studied

Dyspnea

ICD-10 code

R06.0

ICD-10 code description

Dyspnea

Primary outcomes

1

Description

Respiratory distress

Timepoint

Before treatment and up to 40 minutes after treatment

Method of measurement

Physical examination

2

Description

Level of consciousness

Timepoint

Before treatment and up to 40 minutes after treatment

Method of measurement

Glasgow Coma Scale

3

Description

Dyspnea

Timepoint

Before treatment and up to 40 minutes after treatment

Method of measurement

Arterial blood gas test

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Depending on the severity of the dyspnea, they are treated as follows: Use of spray: Salbutamol; Atrovent, injectable corticosteroid use; nebulizer treatment, oxygen therapy, use of injectable beta-agonist, We give diuretic and nitroglycerine serum in patients with symptoms of pulmonary edema.

Category

Treatment - Drugs

2

Description

Intervention group: In addition to the routine treatment in the control group, they are treated with 10 milligram of Diazepam (Cspian Co)(IV injection within a 3 to 4 minute interval).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Simin Najaf Gholian

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Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Morteza Gharibi

Position

Assistant professor, emergency Medicine Specialist

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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Person responsible for updating data**Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Najafgholian

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments