Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 reffering emergency department of Valiasr Hospital and Amiral-Momenin Arak Hospital will inter 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 reffering emergency department of Valiasr Hospital and Amiral-Momenin Arak Hospital will inter 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 ,Pco2 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

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Name of organization / entity
Arak University of Medical Sciences

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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
City
Arak
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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2

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
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Person responsible for updating data

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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