

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the effect of salbutamol nebulizer alone against salbutamol nebulizer and palmicorte in the treatment of patients with bronchospasm after rainfall to the emergency room of imam khomeini in autumn 2020

Protocol summary

Study aim

Determine the effect of salbutamol nebulizer alone against salbutamol nebulizer and palmicorte in the treatment of patients with bronchospasm after rainfall to the emergency room of imam khomeini in ahvaz in autumn 2020

Design

Randomized, double-blind, placebo-controlled clinical trial

Settings and conduct

This study was conducted in Imam Khomeini hospital in Ahvaz as a randomized clinical trial and a 2-group, randomly assigned to one or two envelopes randomly selected.

Participants/Inclusion and exclusion criteria

Inclusion: aged at least 18 years and up to 55 years old.
Exclusion: pregnancy; smoking more than 10 packs per day and sever asthma.

Intervention groups

Comparison of the efficacy of palmicorte and salbutamol concomitantly with the efficacy of salbutamol only on bronchospasm following rainfall.

Main outcome variables

Shortness of breath; increased respiratory rate; decreased arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200109046061N1**

Registration date: **2020-01-19, 1398/10/29**

Registration timing: **prospective**

Last update: **2020-01-19, 1398/10/29**

Update count: **0**

Registration date

2020-01-19, 1398/10/29

Registrant information

Name

Elnaz Nobakht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8617 5194

Email address

dr.elnaznobakht@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of salbutamol nebulizer alone against salbutamol nebulizer and palmicorte in the treatment of patients with bronchospasm after rainfall to the emergency room of imam khomeini in autumn 2020

Public title

Effect of palmicorte in the treatment of patients with

bronchospasm after rainfall

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Must be at least 18 years old and up to 55 years old
Bronchospasm and shortness of breath following rainfall
Exclusion criteria:
Failure to respond to treatment and worsen clinical condition of patients with intravenous magnesium sulfate/epinephrine or intubation(severe asthma)
Pregnant women Smoker patients consuming more than 10 packs per year Beta-agonist nebulizer treatment over the past 6 hours Patients refusal to cooperate during treatment process Underlying pulmonary disease with asthma-like manifestations such as ILD and...

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **228**

Randomization (investigator's opinion)
Randomized

Randomization description
Accidentalize individuals in 40 groups of up to 6 by giving sealed envelopes to 20 other groups form number one envelopes and number envelopes to 20 other groups that we do not know which type in each envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the participants in the project and the researcher were kept blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Faculty of Medicine, Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2019-12-28, 1398/10/07

Ethics committee reference number

IR.AJUMS.REC.1398.684

Health conditions studied

1

Description of health condition studied

Bronchospasm and shortness of breath after the first autumn rains

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak expiratory flow

Timepoint

Before the intervention, 20 mintues after the intervention, 40 minutes later and 60 minutes later

Method of measurement

By using a flow meter pic

2

Description

Forced expiratory volume

Timepoint

Before the intervention, 20 mintues after the intervention, 40 minutes later and 60 minutes later

Method of measurement

By using a flow meter pic

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: salbutamol nebulizer 0.5 mg for 20 minutes 3 times in 60 minutes

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: salbutamol and palmicort nebulizer 0.5 mg for 20 minutes 3 times in 60

minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr. Ali Vefagh Nematollahi

Street address

Imam khomeini Specialized Training Center,
Azadegan Ave., Ahvaz

City

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6193673111

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badavi

Street address

Faculty of Medicine, Ahvaz Jundishapur University of
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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Ali Vefagh Nematollahi

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Ali Vefagh Nematollahi

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Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

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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

Patient information including dyspnea and bronchospasm. How to use the drugs and their effects on patients who are enrolled in the questionnaire and ultimately analyzed. Patient-informed in the study and the names of participants are shared. Do not share with us for patient privacy.

When the data will become available and for how long

The start of the access period after the end of the job is the result of the confirmation

To whom data/document is available

It will be accessible to everyone

Under which criteria data/document could be used

Use salbutamol and palmicort or bronchospasm after rainfall to access this study.

From where data/document is obtainable

Email your requests to alivefagh@yahoo.com

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

Requests email to study person.

Comments