

# 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**

Ahvaz

**Province**

Khuzestan

**Postal code**

6193673111

**Phone**

+98 61 3222 2922

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+98 61 3222 5763

**Email**

dr.elnaznobakht@gmail.com

**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  
Medical Sciences, Golestan Boulevard

**City**

Ahvaz

**Province**

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6155855619

**Phone**

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**Email**

dr.elnaznobakht@gmail.com

**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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Azadegan Ave., Ahvaz

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dr.elnaznobakht@gmail.com

**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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associante professor

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**Email**

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Elnaz Nobakht

**Position**

medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Emergency Medicine

**Street address**

No.104/, Pouya street, 2nd phase, 11west ave.,  
Kianpars

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6155855619

**Phone**

+98 61 3338 7712

**Email**

dr.elnaznobakht@gmail.com

**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**