

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effect of salbutamol spray with its nebulizer in the treatment of acute asthma attacks in children referred to the emergency department of Mofid hospital

Protocol summary

Study aim

Comparison of the effect of salbutamol spray with its nebulizer in the treatment of acute asthma attacks in children referred to the emergency department of Mofid hospital

Design

Clinical trial with control group, with parallel groups in each group 53 patients, without blinding, randomized

Settings and conduct

This clinical trial study will be carried out in children aged 6 months to 14 years of old with acute asthma attack referred to Mofid hospital, and 106 patients were randomly assigned to either salbutamol spray or nebulizer. At the time of referral and at minutes 15, 30, 45 and 60, the respiratory distress assessment scale (RDAS) will be determined. There is no blinding in this study

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 6 months and 14 years of old, Having lung wheezing on auscultation, Score > 4 based on the respiratory distress assessment scale.
Exclusion criteria: Having bronchopulmonary dysplasia, Having cystic fibrosis, Having congenital heart disease, Unwilling to participate in the study

Intervention groups

Intervention group: Salbutamol Nebulizer 0.15 mg / kg every 20 minutes up to three times
Control group: Salbutamol spray 2 to 8 puffs every 20 minutes up to three times

Main outcome variables

Assessment of respiratory distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181102041527N1**

Registration date: **2018-12-23, 1397/10/02**

Registration timing: **retrospective**

Last update: **2018-12-23, 1397/10/02**

Update count: **0**

Registration date

2018-12-23, 1397/10/02

Registrant information

Name

Nazanin Farahbakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2225 1631

Email address

nazanin65farahbakhsh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-02-09, 1394/11/20

Actual recruitment start date

2015-09-23, 1394/07/01

Actual recruitment end date

2016-03-10, 1394/12/20

Trial completion date

2016-03-10, 1394/12/20

Scientific title

Comparison of the effect of salbutamol spray with its nebulizer in the treatment of acute asthma attacks in children referred to the emergency department of Mofid

hospital

Public title
The effect of salbutamol nebulizer in the treatment of acute asthma attack

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 6 months and 14 years of old Having lung wheezing on auscultation Score > 4 based on the respiratory distress assessment scale
Exclusion criteria:
Having bronchopulmonary dysplasia Having cystic fibrosis Having congenital heart disease Unwilling to participate in the study

Age
From **6 months** old to **14 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **106**
Actual sample size reached: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
Assignment of patients in two groups of intervention and control was done by Block Balanced Randomization (BBR) method. The Randomization Sequence was generated using the free website at <http://www.randomization.com>.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Daneshjou Blvd, District 1, Tehran, Tehran province

City

Tehran

Province

Tehran

Postal code
1983969411

Approval date
2015-03-29, 1394/01/09

Ethics committee reference number
IR.SBMU.SM.REC.1394.19

Health conditions studied

1

Description of health condition studied

Asthma attack of children

ICD-10 code

J45.90

ICD-10 code description

Unspecified asthma

Primary outcomes

1

Description

Assessment of respiratory distress

Timepoint

At the time of referral and at minutes 15, 30, 45 and 60

Method of measurement

Respiratory Distress Assessment Scale (RDAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Salbutamol Nebulizer is given as 0.15 mg / kg every 20 minutes up to three times, and then the score for the assessment of respiratory distress is calculated.

Category

Treatment - Drugs

2

Description

Control group: Salbutamol spray 2 to 8 puffs every 20 minutes up to three times is given, and then the score for the assessment of respiratory distress is calculated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid hospital

Full name of responsible person

Seyyed Ahmad Tabatabayi

Street address

Shariati St, District 3, Tehran, Tehran Province

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Province

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1546815514

Phone

+98 21 2222 7029

Email

Ahmadtabatabaii@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Deputy of research and technology of Shahid Beheshti University of Medical Sciences

Street address

Daneshjou Blvd, District 1, Tehran, Tehran province

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Province

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Postal code

1983969411

Phone

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Email

info@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nazanin Farahbakhsh

Position

Fellowship

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Pediatric department, Mofid children's hospital, Shariati street

City

Tehran

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nazanin65farahbakhsh@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nazanin Farahbakhsh

Position

Fellowship

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Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nazanin Farahbakhsh

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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

After completion of the study, I will publish it

When the data will become available and for how long

Twelve months

To whom data/document is available

Faculty members and students

Under which criteria data/document could be used

Request through email

From where data/document is obtainable

Email to nazanin26farahbakhsh@yahoo.com

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

Email to nazanin26farahbakhsh@yahoo.com

Comments