Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 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
City
Tehran
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Tehran
Postal code
1546815514
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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
City
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
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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