Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of response to treatment and comparison of normal saline and hypertonic saline nebulizer in the bronchiolitis

Protocol summary

Study aim

Evaluation of response to treatment and comparison of normal saline and hypertonic saline nebulizer in the bronchiolitis

Design

The design of the study is a randomized clinical trial. The randomization method is blocked. The sample size for each study group is 60.

Settings and conduct

All patients referred to the Ali Asghar Hospital, who suffered from bronchiolitis will be enrolled. Patients will be randomly divided into two groups based on 10 blocks. A total of 60 patients will be examined. Patients and data analyzer will be blind.

Participants/Inclusion and exclusion criteria

All patients referred to the Ali Asghar Hospital, who suffered from bronchiolitis will be enrolled. Inclusion criteria: patients over 1year, Clinical evidence of respiratory viral infection, Body temperature 38 degrees Celsius and above, Abnormal breathing rate based on age range, High heart rate due to age range, coryza. Exclusion criteria: Patients over 10 years old, History of more than two episodes of respiratory distress in the past, Chronic heart and pulmonary disease, Safety defect, Down syndrome, Metabolic or neurological disease Use of mechanical ventilation in neonatal period, Positive family history of asthma, Sick patient requiring immediate hospitalization due to dehydration, decreased consciousness, lethargy, or respiratory failure symptoms

Intervention groups

In control group Patients will receive 3 ml normal saline 0.9% each 20 minutes for 3 times and 8 liters of oxygen per minute via nebulizer. In intervention group Patients will receive 3 ml of hypertonic saline 3%, each 20 minutes for 3 times and 8 liters of oxygen per minute via nebulizer.

Main outcome variables

The number of pulses,The number of pulses, Breath rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151003024317N6**
Registration date: **2019-08-19, 1398/05/28**
Registration timing: **prospective**

Last update: **2019-08-19, 1398/05/28**
Update count: **0**

Registration date

2019-08-19, 1398/05/28

Registrant information

Name

Mahdi Rezai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8868 6772

Email address

rezaei.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-16, 1398/06/25

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of response to treatment and comparison of normal saline and hypertonic saline nebulizer in the bronchiolitis

Public title
Treatment of bronchiolitis
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical evidence of respiratory viral infection Body temperature 38 degrees Celsius and above Abnormal breathing rate based on age range High heart rate due to age range coryza Age over 1 year
Exclusion criteria:
History of more than two episodes of respiratory distress in the past, Chronic heart and pulmonary disease Safety defect Down syndrome Metabolic or neurological disease Use of mechanical ventilation in neonatal period Positive family history of asthma Sick patient requiring immediate hospitalization due to dehydration, decreased consciousness, lethargy, or respiratory failure symptoms Age over 10 years
Age
From **1 year** old to **10 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to two groups. In order to randomize, a random block method will be used. For this purpose, we formed blocks with 10 person. In each block, 5 individuals will be in intervention group and 5 will be in control group. A total of 6 blocks will be considered for sample size.
Blinding (investigator's opinion)
Double blinded
Blinding description
Data will be analyzed by person who is blind to study groups, and patients will also be unaware of the type of treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Shahid Hemmat highway, Tehran,Iran.
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-10-23, 1397/08/01
Ethics committee reference number
IR.IUMS.FMD.REC.1397.123

Health conditions studied

1

Description of health condition studied
Bronchiolitis
ICD-10 code
J21
ICD-10 code description
Acute bronchiolitis

Primary outcomes

1

Description
Saturation of oxygen
Timepoint
On arrival, 10 minutes after the first nebulizer, 10 minutes after the second nebulizer; 10 minutes after the third nebulizer
Method of measurement
Pulse Oximetry

2

Description
The number of pulses
Timepoint
On arrival, 10 minutes after the first nebulizer, 10 minutes after the second nebulizer; 10 minutes after the third nebulizer
Method of measurement
Based on patient records

3

Description
Breath rate
Timepoint
On arrival, 10 minutes after the first nebulizer, 10

minutes after the second nebulizer; 10 minutes after the third nebulizer

Method of measurement

Based on patient records

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients will receive 3 ml normal saline 0.9% each 20 minutes for 3 times and 8 liters of oxygen per minute via nebulizer.

Category

Treatment - Drugs

2

Description

Intervention group: Patients will receive 3 ml of hypertonic saline 3%, each 20 minutes for 3 times and 8 liters of oxygen per minute via nebulizer.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Hospital

Full name of responsible person

Samane Sadat Khoobbin Khoshnazar

Street address

Ali Asghar Children's Hospital, Shaheed Dastgerdi Street (Zafar),

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2222 2042

Email

aach@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem Malakooti

Street address

Shahid Hemmat highway, Tehran,Iran.

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

research@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Samane Sadat Khoobbin Khoshnazar

Position

Emergency medicine specialist

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Shahid Hemmat highway, Tehran,Iran.

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Email

Samanekhoshnazar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person
Seyedeh Mahsa Mahmoudi Nejad Dezfuli
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Shahid Hemmat highway, Tehran,Iran.
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
mahmoudinejad.m@ums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyedeh Mahsa Mahmoudi Nejad Dezfuli
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Shahid Hemmat highway, Tehran,Iran.
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
mahmoudinejad.m@ums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available