

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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 1 year, 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),

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Seyedeh Mahsa Mahmoudi Nejad Dezfuli

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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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

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

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Latest degree

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Other areas of specialty/work

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