

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

the effect of Nebulized Hypertonic3% Saline in the Treatment of Acute bronchiolitis in pediatric ward

Protocol summary

Summary

Objectives: Determination of effect of nebulized Hypertonic3% Saline in the Treatment of Acute bronchiolitis. Design: Double blind, control with placebo, single center, stage 2 trail. Setting and conduct: 70 acute bronchiolitis patients in Pediatric ward in Hajar Hospital in Shahrekord randomly assigned into two groups: experiment and control groups. Participants: Inclusion criteria are diagnosis of bronchiolitis, admission in Pediatric ward. exclusion criteria: any underlying disease (e.g., cystic fibrosis, bronchopulmonary dysplasia and cardiac or renal disease, wheezing, atopic dermatitis, allergic rhinitis or asthma, oxygen saturation (SaO₂) <85% on room air, progressive respiratory failure requiring mechanical ventilation, previous treatment with bronchodilators, and any steroid therapy within 2 weeks. Interventions: Intervention group get nebulized Hypertonic3% Saline . The control group get nebulized ventolin for the same time with intervention group . Intervention period: Two weeks. main outcome measures: bronchiolitis symptoms

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012110510222N2**

Registration date: **2013-01-28, 1391/11/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-01-28, 1391/11/09

Registrant information

Name

Zahra Keivani

Name of organization / entity

Shahrekord University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1222 0016

Email address

keivani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shahrekord University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of Nebulized Hypertonic3% Saline in the Treatment of Acute bronchiolitis in pediatric ward

Public title

the effect of Nebulized Hypertonic3% Saline in the Treatment of Acute bronchiolitis in pediatric ward

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of bronchiolitis, admission in Pediatric ward, Exclusion criteria: any underlying disease (e.g., cystic fibrosis, bronchopulmonary dysplasia and cardiac or renal disease, wheezing, atopic dermatitis, allergic rhinitis or asthma, oxygen saturation (SaO₂) <85% on room air, progressive respiratory failure

requiring mechanical ventilation, previous treatment with bronchodilators, and any steroid therapy within 2 weeks.

Age

To 2 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Ethics Committee, Shahrekord University of Medical Sciences, Kashani Street

City

Shahrekord

Postal code

Approval date

2013-01-08, 1391/10/19

Ethics committee reference number

24-10-91

Health conditions studied

1

Description of health condition studied

brochiolitis

ICD-10 code

J21.0

ICD-10 code description

Acute bronchiolitis due to respiratory syncytial virus

Primary outcomes

1

Description

bronchiolitis symptom

Timepoint

at base line, two weeks later

Method of measurement

examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 2 weeks, get hypersalin 3%.

Category

Treatment - Drugs

2

Description

Control group: 2 weeks, get ventolin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital Shahrekord

Full name of responsible person

Zahra Keivani

Street address

Shahrekord, Shahrekord University of Medical Sciences

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Mahmoud Mobasheri

Street address

Vice Chancellor for Research, Shahrekord University of Medical Sciences, Kashani Street

City

Shahrekord

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Shahrekord Univrsity of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Shahrekord University Of Medical Sciences

Full name of responsible person

Zahra Keivani

Position

Master of Nursing

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Shahrekord University Of Medical Sciences

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Zahra Keivani

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Fax**Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*