

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of budesonide nebulizer on healing and treatment process of children with pneumonia aged 1 month to 5 years: a randomized clinical trial

Protocol summary

Study aim

Investigating the effect of budesonide nebulizer on the recovery and treatment of children with pneumonia from 1 month to 5 years

Design

Clinical trial with control group, with parallel groups, randomized, phase 3 on 122 patients. Random permutation method with the size of 2, 4 and 6 random blocks was used for randomization.

Settings and conduct

the trial will be conducted at Hajar Hospital in Shahrekord city. Blood sample will be taken for CBC, ESR, CRP. The PRESS score is calculated and the samples are divided into 3 groups based on the severity of pneumonia: mild, moderate and severe. PRESS score and its content, number of coughs during the day will be calculated during hospitalization. At the end of intervention, CBC, ESR, CRP will be checked again and the days of hospitalization will be recorded. the control and intervention groups then will be compared based on the severity of the disease.

Participants/Inclusion and exclusion criteria

Inclusion: age between 1 month and 5 years, diagnosis of community-acquired pneumonia by a pediatric specialist, complete symptoms, informed consent of the child's family to enter the study. Exclusion: presence of metabolic, cardiopulmonary or hypersensitivity airway disease, discontinuation of standard treatment for any possible reason, children with abnormal coagulation function, psychological disorder, diabetes and immunodeficiency and unwillingness to Continue treatment

Intervention groups

In the intervention group, a dose of 0.5 mg of Budesonide nebulizer of Pulmicort brand will be used every 12 hours for 5 days. Common interventions will be used in the control group (not receiving budesonide

nebulizer).

Main outcome variables

Duration of hospitalization, duration of fever, duration of cough, duration of need for intravenous fluids, duration of wheezing, PREES score, oxygen saturation level, respiratory status and laboratory factors (WBC, ESR, CRP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240204060891N1**

Registration date: **2024-02-15, 1402/11/26**

Registration timing: **prospective**

Last update: **2024-02-15, 1402/11/26**

Update count: **0**

Registration date

2024-02-15, 1402/11/26

Registrant information

Name

Mahsa Banitalebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

st-banitalebi@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2024-10-11, 1403/07/20

Actual recruitment start date

2024-03-05, 1402/12/15

Actual recruitment end date

2024-10-11, 1403/07/20

Trial completion date

2024-10-20, 1403/07/29

Scientific title

Investigating the effect of budesonide nebulizer on healing and treatment process of children with pneumonia aged 1 month to 5 years: a randomized clinical trial

Public title

Investigating the effect of budesonide nebulizer on healing and treatment process of children with pneumonia aged 1month to 5 years: a randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 1 month to 5 years community acquired pneumonia diagnosed by pediatrician Informed consent of the child's family to enter the study Observing and recording complete symptoms of patient during treatment

Exclusion criteria:

Metabolic disorder cardiovascular disorder hyper reactive airway disease coagulopathy psychological disorder diabetes Immunocompromised patients Discontinuation of standard treatment for any possible reason Reluctance to continue treatment

Age

From **1 month** old to **5 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **110**

Actual sample size reached: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation of participants into 2 groups will be done randomly and by block method. The random assignment sequence is performed using a computer program. The random permutation method with the size of random blocks 2, 4, and 6 (because the last person in each block is not known) will be used to assign people to two groups receiving medicine, including 61 people, and the control group, including 61 people.

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 shahrekord University of Medical Sciences

Street address

Clinical Research Development Unit of Hajar Hospital, Shahrekord, Nurse St., Hajar Hospital

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816854633

Approval date

2023-11-15, 1402/08/24

Ethics committee reference number

IR.SKUMS.MED.REC.1402.067

Health conditions studied

1

Description of health condition studied

community acquired pneumonia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Average score of PRESS

Timepoint

Measuring the PRESS score before the study, on days 1, 2, 3, 4, and 5 and after the end of the trial

Method of measurement

Pediatric Respiratory Severity Score (PRESS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: budesonide recipient group

Category

Treatment - Drugs

2

Description

Control group: The group not receiving budesonide

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital

Full name of responsible person

Mahsa Banitalebi

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Hajar Hospital Clinical Research Development Unit,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr.Seyyed Mohammad Omrani

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Hajar-Hospital@SKUMS.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Mahsa Banitalebi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Shahre-kord University of Medical Sciences

Full name of responsible person

Javad Fadaee Tehrani

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Associate professor

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Specialist

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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

Not applicable

Title and more details about the data/document

The information obtained from the patients includes height, weight, BMI, hospitalization history, smoking and smoking in the family, urban or rural residence, and can be shared

When the data will become available and for how long

Access period starts 6 months after publication

To whom data/document is available

our Data available for Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Data analysis is allowed only for research purposes in centers and academic institutions and academies in compliance with medical ethics

From where data/document is obtainable

The application should be submitted to the email below and the applicant's information including the name and surname, academic degree and academic or research center of the individual should be sent

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

After sending the email, your request will be answered within 1 working week

Comments