

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Determining the effect of vitamin A on persistent wheezing of infants with bronchiolitis admitted to Ali ibn Abi Talib hospital of Zahedan

Protocol summary

Study aim

Determining the Effect of Vitamin A on persistent wheezing of Infants with bronchiolitis admitted to Ali ibn Abi Talib hospital of Zahedan

Design

A randomized, without blindness, sham-controlled clinical trial with a parallel group postoperative care and outcome assessment, design of 60 patients, enrolled between March 2018 and March 2019 and followed for one year

Settings and conduct

This study will be performed in Imam Ali Hospital in Zahedan. 60 infants aged 1 month to 2 years are included in the study after confirming of bronchiolitis by a specialist and no history of previous disease. Patients will be divided into two groups of case and control with random blocks. Then, the patient's demographic information and severity of symptoms will be recorded. For both groups, the usual treatment of bronchiolitis and for the case group also 5,000 units per kg of body weight of the injected vitamin A will be prescribed. Then, all patients will be visited regarding severity of symptoms by one assisted pediatrician, 24 hours after injection (during hospitalization), at the time of discharge, and 2 weeks after that.

Participants/Inclusion and exclusion criteria

After getting history and performing a physical examination, Infants with bronchiolitis from one month to two years were included to the study and patients with a history of congenital heart disease, pulmonary, asthma or other immunodeficiencies and other chronic diseases, also if the diagnose changed during this study, were excluded.

Intervention groups

The intervention group consists of 30 infants who receive the usual treatment of Bronchiolitis, such as Cold Oxygen Steam and Bronchodilator and 5,000 units per kg body weight of injected vitamin A.

Main outcome variables

severity of wheezing, retraction status, respiratory rate, and general condition of the patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180425039418N5**

Registration date: **2019-03-04, 1397/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-04, 1397/12/13**

Update count: **0**

Registration date

2019-03-04, 1397/12/13

Registrant information

Name

mohammad Ghena'at Pisheh Sanani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3343 1227

Email address

mohammad.ghenaat71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of vitamin A on persistent wheezing of infants with bronchiolitis admitted to Ali ibn Abi Talib hospital of Zahedan

Public title

vitamin A effect on post bronchiolitis wheezing

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infants with a history of upper respiratory tract infection (runny nose - cough) with increased respiratory effort and abnormal auditory findings. Acquiring informed consent of parents Being Term at birth Normal weight at birth and during admission Not having chronic or congenital lung, cardiac, neurological diseases and immune deficiency No vitamin A intake before entering to the study

Exclusion criteria:

Other diagnoses for the patients during admission Parental dissatisfaction to continue participating in the study

Age

From **1 month** old to **2 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The random blocks method was used (based on the preliminary estimate of the number of clients in December 2016 and the first 3 months of 2018)

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 Zahedan University of Medical

Sciences

Street address

Campus of Medical Scineces, Dr.Hesabi Squar

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2018-03-20, 1396/12/29

Ethics committee reference number

IR.ZAUMS.REC.1396.14

Health conditions studied**1****Description of health condition studied**

Bronchiolitis

ICD-10 code

J21.9

ICD-10 code description

Acute bronchiolitis, unspecified

2**Description of health condition studied**

Post Bronchiolitis Wheezing

ICD-10 code

R06.2

ICD-10 code description

Wheezing

Primary outcomes**1****Description**

Severity of wheezing in bronchiolitis

Timepoint

At 24 hours after the injection (during the patient's hospitalization), during discharge and two weeks after discharge

Method of measurement

Littmann Stethoscope 3M

Secondary outcomes

empty

Intervention groups**1****Description**

"Intervention group:" Includes 30 infants from one month to two years old with the first episode of Bronchiolitis referring to Ali ibn Abi Talib Hospital in Zahedan, prescribed with 5,000 units per kilogram body weight of injected vitamin A.

Category

Treatment - Drugs

2

Description

Control group: No additional work

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-ibn-Abitaleb Hospital

Full name of responsible person

Gholamreza Soleimani

Street address

Salamat Blvd, Persian Gulf Expressway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Alireza Ansari Moghaddam

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Afsaneh Mirshekari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no information yet

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available