

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effects of vitamin D in pneumonia treatment in hospitalized children, double-blind randomized clinical trial

Protocol summary

Summary

Purpose: using of vitamin D more than the usual dose can be effective in prevention or incidence of respiratory infections in children. There is no consensus on the antimicrobial mechanisms of vitamin D But some researchers have suggested that vitamin D can be effective through increased production of some proteins involved in innate immunity. This study aimed to evaluate the effect of single dose prescription of vitamin D in the course of respiratory infections in children hospitalized in Ardabil Bu Ali hospital and its relationship with blood levels of the vitamin D active forms. Design and implementation : In this study , 80 children aged 6 months to 6 years with bacterial pneumonia hospitalized in Bu Ali hospital divided into two groups randomly. Participants included the main inclusion and exclusion criteria: bacterial pneumonia, the age of six months to six years, hospitalization in the Bu Ali hospital , parental consent. Exclusion criteria included: Rickets, other associated infectious diseases such as meningitis, active and hidden tuberculosis, viral pneumonia , consumption of vitamin D with high-dose in the last three months, severe malnutrition and underlying diseases such as cystic fibrosis and metabolic syndromes. Intervention: first group recieved 100000 IU of oral single dose of vitamin D and second group as control were selected randomly and received sweet almond oil as a placebo.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052617843N2**

Registration date: **2014-07-26, 1393/05/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-26, 1393/05/04

Registrant information

Name

Adel Ahadi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1773 1210

Email address

a.ahadi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences.

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of vitamin D in pneumonia treatment in hospitalized children, double-blind randomized clinical trial

Public title

The effect of vitamin D in hospitalized children for respiratory infection treatment.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged six months to six years; Hospitalization in Bu Ali hospital with bacterial pneumonia; parental consent. Exclusion criteria: Rickets; along with other infectious diseases such as meningitis; tuberculosis; viral pneumonia; the use of high-dose vitamin D in the last three months; severe malnutrition and diseases such as cystic fibrosis and metabolic syndrome.

Age

From **6 months** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Ardabil University of Medical Sciences

Street address

Ardabil, Daneshgah Street, Ardabil University of Medical Sciences.

City

Ardabil

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

9190

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

Pneumonia

ICD-10 code

J12

ICD-10 code description

Viral pneumonia, not elsewhere classified

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

Disease Improvement.

Timepoint

12 weeks.

Method of measurement

Chest radiography.

Secondary outcomes**1****Description**

Interferon gamma

Timepoint

10 days.

Method of measurement

Folin-Ciocalteu reagent

2**Description**

IL-6

Timepoint

10 days.

Method of measurement

ELISA method.

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

In this study to intervention group, prescribed vitamin D vial 100000 IU, orally, once.

Category

Treatment - Drugs

2**Description**

In this study to placebo group, prescribed Sweet oil vial, orally, once.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bo Ali Hospital

Full name of responsible person

Dr adel ahadi

Street address

City
Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Hadi Piri dogahe

Street address

Ardabil, Daneshgah Street, Ardabil University of Medical Sciences.

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil University 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

Ardabil University of Medical Sciences.

Full name of responsible person

Dr Adel Ahadi

Position

Professor of Pediatrics

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Boali Hospital

Full name of responsible person

Dr Shahab Bohlooli

Position

Pharmacology Phd

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

dr Asefe Mortazavi

Position

pediatric assistant

Other areas of specialty/work

Street address

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Phone

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