

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of vitamin C administration on improving pneumonia in children 2 to 12 years of age

Protocol summary

Study aim

Investigating the effect of single dose of vitamin C on improving pneumonia in children 2 to 12 years of age

Design

Clinical trial with control group, two arm parallel group randomised trial with blinded, randomized, phase 3 on 100 patients. www.randomization.com was used to randomize

Settings and conduct

The study was performed on children aged 2 to 12 with hospitalized pneumonia at Dr. Sheikh Hospital, which is divided into two groups: case and control. The control group received a single dose of placebo and the case group received a single dose of 500 mg of vitamin C. Participants and evaluators do not know are being in which group.

Participants/Inclusion and exclusion criteria

Children 2 to 12 years of age with pneumonia with no history of cystic fibrosis, bronchiectasis, acute and chronic renal failure, malnutrition, vitamin C intake in the past month, congenital heart disease, and mechanical ventilation

Intervention groups

Prescribing vitamin C as a single dose of 500 mg to children aged 2 to 12 years with pneumonia

Main outcome variables

A Fever, tachypnea, cyanosis, respiratory distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101106005114N3**

Registration date: **2020-06-18, 1399/03/29**

Registration timing: **prospective**

Last update: **2020-06-18, 1399/03/29**

Update count: **0**

Registration date

2020-06-18, 1399/03/29

Registrant information

Name

Farhad Heydarian

Name of organization / entity

Mashhad university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1801 2469

Email address

heydarianf@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of vitamin C administration on improving pneumonia in children 2 to 12 years of age

Public title

The effect of vitamin C in the treatment of pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children 2 to 12 years of age who have been given a

definitive diagnosis of pneumonia according to clinical signs and graphics

Exclusion criteria:

Existence of underlying disease such as cystic fibrosis, bronchiectasis, acute or chronic kidney disease Vitamin C intake over the past 1 month The patient is intubated

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method has been used. This method is done through a table of random numbers using the site www.randomization.com. Accidental hiding was done using closed envelopes in such a way that the envelopes were prepared and printed by one of the members of the research team and random numbers with the help of the above site and inside the envelope. The envelopes were closed and the contents could not be seen from the outside. First, the purpose of the study was explained to the person who meets the conditions, and if desired, the person signed a conscious consent form, took an envelope and opened it, and entered the intervention or control group based on the contents of the person's envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Failure to inform the participant and evaluate the result

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

No. 23, Daneshgah Ave., Mashhad., Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

917351358

Approval date

2018-04-11, 1397/01/22

Ethics committee reference number

IR.mums.medical.rec.1397.011

Health conditions studied

1

Description of health condition studied

Pneumonia

ICD-10 code

J15.9

ICD-10 code description

Unspecified bacterial pneumonia

Primary outcomes

1

Description

Evaluation of fever every 6 hours by the evaluator and registration in the file

Timepoint

6, 12, 18, 24, 30, 36, 42, 48, 54, 60 hours

Method of measurement

Assessment of fever through an axillary thermometer

2

Description

Evaluate the number of breaths every 6 hours by the evaluator and record in the file

Timepoint

6, 12, 18, 24, 30, 36, 42, 48, 54, 60 hours

Method of measurement

Evaluation of the number of breaths through clinical examination and counting the number of breaths per minute by the evaluator and registration in the file

3

Description

Evaluation of Oxygen saturation level every 6 hours by the evaluator and record in the file

Timepoint

6, 12, 18, 24, 30, 36, 42, 48, 54, 60 hours

Method of measurement

Evaluation of oxygen saturation level through oximeter pulse by the evaluator and registration in the file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving a single dose of vitamin C 500 mg.

Category

Treatment - Drugs

2

Description

Control group:receiving placebo as a single dose and in terms of drug form is quite similar to vitamin C 500 mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Sheikh Hospital

Full name of responsible person

Farhad Heydarian

Street address

No 3 , Dr. Sheikh Street

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Email

HeydarianF@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen tafaghodi

Street address

No. 23, Daneshgah Ave.,Mashhad., Iran

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Email

TafaghodiM@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

80

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

Mashhad University of Medical Sciences

Full name of responsible person

Farhad Heydarian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farhad Heydarian

Position

Professor

Latest degree

Specialist

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Person responsible for updating data

Contact

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Full name of responsible person
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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

Yes - There is a plan to make this available

Title and more details about the data/document

The results of the study, such as the effect of vitamin C on the improvement of clinical symptoms of pneumonia, such as fever and tachypnea and cyanosis, in both case and control groups

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions, medical students

Under which criteria data/document could be used

At the request of researchers working in academic and scientific institutions, medical students

From where data/document is obtainable

To the author in charge of the article, Dr. Farhad Heydarian

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

Request emails to the corresponding author

Comments