Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effect of synbiotic on prevention of viral upper respiratory infections in children with mild intermittent asthma

Protocol summary

Summary

Seventy two children with mild persistent asthma aged between 6 to 12 years randomly divide to receive either the Lactocare®, a Synbiotic containing 1 billion CFU/Capsule of: Lactobacillus casei, Lactobacillus rhamnosus, Streptococcus thermophilus, Bifidobacterium breve, Lactobacillus acidophilus, Bifidobacterium infantis, Lactobacillus bulgaricus and Fructooligosacharide (Zist Takhmir, Tehran, Iran) or placebo daily for 60 days. The primary outcome measure is the number of viral infection episodes and Secondary outcome measures are including: school absent, Salbutamol use, Prednisolone use, outpatient visits and hospital admission.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509234976N3**
Registration date: **2015-10-22, 1394/07/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-10-22, 1394/07/30

Registrant information

Name
Hamid Ahanchian
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 51 3801 2469
Email address
ahanchianh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor for research, Mashhad University of medical sciences.

Expected recruitment start date

2013-06-01, 1392/03/11

Expected recruitment end date

2015-06-01, 1394/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of synbiotic on prevention of viral upper respiratory infections in children with mild intermittent asthma

Public title

Synbiotic for prevention of common cold in asthmatic children

Purpose

Treatment

Inclusion/Exclusion criteria

Children with mild persistent asthma aged between 6 to 12 years with a history of recurrence (at least two viral upper respiratory infections in past autumn) entered the study. Those with congenital abnormalities or syndromes, antibiotic or probiotic consumption during 2 weeks before study and any underlying disease were excluded

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **72**
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
Ethic committe of Mashhad university of Medical Sciences
Street address
Ghoreyshi Building, Daneshgah streeet, Mashhad Iran
City
Mashhad
Postal code
Approval date
2013-04-17, 1392/01/28
Ethics committee reference number
911048

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
J45
ICD-10 code description
Asthma

Primary outcomes

1

Description
Number of episodes of viral respiratory infection
Timepoint
Drring 8 weeks of study
Method of measurement
Clinical visit

Secondary outcomes

1

Description
Salbutamol and prednisolone use - outpatient visit - Hospital Addmision
Timepoint
During 8 weeks of study
Method of measurement
Clinical visit

Intervention groups

1

Description
Intervention group :Lactocare®, a Synbiotic capsule containing 1 billion CFU/Capsule of: Lactobacillus casei, Lactobacillus rhamnosus, Streptococcus thermophilus, Bifidobacterium breve, Lactobacillus acidophilus, Bifidobacterium infantis, Lactobacillus bulgaricus and Fructooligosacharide (Zist Takhmir, Tehran, Iran) one capsule daily for 2 months
Category
Treatment - Drugs

2

Description
Control group : Placebo capsule with same size and shape, one capsule daily for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sarvar Children Hospital
Full name of responsible person
Dr. Hamid Ahanchian
Street address
Ghaem hospital, Ahmad abad Ave., Mashhad, Iran
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice chancellor for research, Mashhad University of medical sciences.
Full name of responsible person
Dr Ramezani
Street address
Ghoreishi bulding, Daneshgah street, Mashhad, Iran

Mashhad Khorasan Iran, Islamic Republic Of

City

Mashhad

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, Mashhad 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Ahanchian

Position

Associate Professor

Other areas of specialty/work

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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