Clinical Trial Protocol
Iranian Registry of Clinical Trials
20 Jul 2020

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: empty
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
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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 commitee of Mashhad university of Medical Sciences
Street address
Ghoreyshi Building, Daneshgah street, 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
During 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
Ghoreisshi 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

Person responsible for updating data

Contact

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