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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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 comittee 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 Admission
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
Ghoreish building, Daneshgah street, Mashhad, Iran
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
empty
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