ISRCTN16959643 https://doi.org/10.1186/ISRCTN16959643

Lactobacillus GG in prevention of gastrointestinal and respiratory tract infections in healthy children: Randomised, double-blind, placebo-controlled study

Submission date
29/01/2008

Registration date
11/04/2008

Last Edited
02/12/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Iva Hojsak

Contact details
Children's Hospital Zagreb
Klaiceva 16
Zagreb
Croatia
10000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Probiotics are defined as live microorganisms which confer a beneficial health effect on a human host.
The most commonly used probiotics are bacteria of genera Lactobacillus or Bifidobacterium. A probiotic preparation must contain a certain minimum number of Colony-Forming Units (CFU) per dose. Doses used in therapeutic and preventive trials vary (106 to 109 CFUs). There is an increasing number of studies on beneficial effects of probiotics in treatment of acute infectious diarrhoea and prevention of antibiotic associated diarrhoea. However, the role of probiotics in prevention of nosocomial diarrhoea is still controversial.

Probiotics can also be used as preventive measure in gastrointestinal and respiratory tract infection, and although currently randomised controlled trials show a modest effect, future large, prospective studies are necessary.

Study hypothesis:
Use of probiotics can effectively reduce the risk of nosocomial gastrointestinal and respiratory infections in healthy children in kindergarten.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Children's Hospital Ethics Committee Zagreb, Klaiceva 16, 10000 Zagreb, Croatia. Date of approval: 22/02/2007 (ref: 01-57/3-1-07)

Study design
Randomized, double-blind, placebo controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Gastrointestinal and respiratory tract infections in children

Interventions
All children at kindergarten whose parents have signed an inform consent, would be randomly assigned into one of two following groups:
1.Group A will receive LGG at a dose 10^10 CFU per day in fermented milk product for three months
2.Group B will receive placebo (fermented milk product) daily for three months

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following will be assessed after 3 months of intervention:
1. Rate of gastrointestinal tract infections including diarrhea (defined as 3 or more loose or watery stools in 24 hours) and vomiting
2. Rate of upper respiratory tract infections including rhinitis, pharyngitis, otitis, common cold and sinusitis
3. Rate of lower respiratory tract infections including pneumonia, bronchitis and bronciolitis (diagnosis by physician)
4. Duration of gastrointestinal and respiratory tract infections

Secondary outcome measures
The following will be assessed after 3 months of interventions:
1. In participants with gastrointestinal tract infections:
1.1. Duration of symptoms
1.2. Number of stools or vomiting episodes
1.3. Number of infections with determined infective cause: Nature of infective etiology

2. In participants with respiratory tract infections:
2.1. Duration of symptoms (cough, fever)
2.2. Severity of infection (mild, moderate, severe)
2.3. Need for antibiotics
2.4. Number of infections with determined infective cause: Nature of infective etiology

Overall study start date
20/11/2007

Completion date
20/02/2008

Eligibility

Key inclusion criteria
All children attending day care at two kindergartens located in the Zagreb city centre with approximately 300 children, age from 12 months to 7 years.

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Months

Upper age limit
7 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Immunodeficiency
2. Cow's milk allergy (probiotics will be given in fermented cow's milk product)
3. Receiving infant formula containing probiotics and/or prebiotics at the time of enrolment
4. Receiving probiotic and/or prebiotic products prior to enrolment (7 days prior to hospitalization)
5. Neoplasms
6. Chronic disorders

Date of first enrolment
20/11/2007

Date of final enrolment
20/02/2008

Locations

Countries of recruitment
Croatia

Study participating centre
Children's Hospital Zagreb
Zagreb
Croatia
10000

Sponsor information

Organisation
Dukat (Croatia)

Sponsor details
M Cavica 9
Zagreb
Croatia
10000

Sponsor type
Industry

Website
http://www.dukat.hr

ROR
https://ror.org/05ceh6345

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Children's Hospital Zagreb (Croatia)

Funder Name
Dukat (Croatian milk company) will donate probiotics and fermented milk products

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2010		Yes	No