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

Submission date
29/01/2008

Recruitment status
No longer recruiting

Registration date
11/04/2008

Overall study status
Completed

Last Edited
25/05/2010

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

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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.

Hypothesis:
Use of probiotics can effectively reduce the risk of nosocomial gastrointestinal and respiratory infections in acutely ill children.

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)

Primary study design
Interventional

Study design
Randomised, double-blind, placebo controlled study.

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Gastrointestinal and respiratory tract infections in children

Interventions
All hospitalised children at the Paediatrics Department whose parents have signed an inform consent will be randomly assigned into one of the two following groups:
Group A: Children will receive Lactobacillus GG at a dose 10^10 CFU per day in fermented milk product during hospitalization
Group B: Children will receive placebo (Post-pasteurized fermented product with similar taste to the active product) daily during hospitalization

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lactobacillus GG

Primary outcome(s)
The following will be monitored during hospitalization and reassessed 7 days after discharge from hospital:
1. Rate of gastrointestinal tract infections including diarrhea (defined as 3 or more loose or watery stools in 24 hours), vomiting
2. Rate of upper respiratory tract infections including rhinitis, pharyngitis, otitis and common cold
3. Rate of lower respiratory tract infections including pneumonia, bronchitis and bronciolitis (diagnosis by physician)
4. Duration of gastrointestinal and respiratory infections
5. Total duration of hospitalisation at the Paediatric Department

Key secondary outcome(s)
The following will be monitored during hospitalization and reassessed 7 days after discharge from hospital:
1. In patients 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
1.4. Duration of hospitalisation at the Paediatric Department

2. In patients 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
2.5. Duration of hospitalisation at the Paediatric Department

Completion date
20/05/2008

Eligibility

Key inclusion criteria
1. All paediatric patients hospitalised during the period of 6 months at the Department of Paediatrics, Children's Hospital Zagreb
2. Age from 12 months to 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
All

Key exclusion criteria
1. Immunodeficiency
2. Infants from neonatal period until 9th month of age
3. Cow's milk allergy (probiotics will be given in fermented cow's milk product)
4. Re-hospitalisation
5. Receiving infant formula containing probiotics and/or prebiotics at the time of enrolment
6. Receiving probiotic and/or prebiotic products prior to enrolment (7 days prior to hospitalisation)
7. Children admitted due to acute gastrointestinal or respiratory infections
8. Neoplasms
9. Chronic disorders

Date of first enrolment
20/11/2007

Date of final enrolment
20/05/2008

Locations

Countries of recruitment
Croatia

Study participating centre
Children's Hospital Zagreb
Zagreb
Croatia
10000

Sponsor information

Organisation
Dukat (Croatia)

ROR
https://ror.org/05ceh6345

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Children's Hospital Zagreb (Croatia)

Results and Publications

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	01/05/2010		Yes	No