

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	<input type="checkbox"/> Prospectively registered
Registration date 11/04/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/05/2010	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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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.

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, Klaićeva 16, 10000 Zagreb, Croatia. Date of approval: 22/02/2007 (ref: 01-57/3-1-07)

Study design

Randomised, 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 hospitalised children at the Paediatrics Department whose parents have signed an informed 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 measure

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 bronchiolitis (diagnosis by physician)
4. Duration of gastrointestinal and respiratory infections
5. Total duration of hospitalisation at the Paediatric Department

Secondary outcome measures

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

Overall study start date

20/11/2007

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

Age group

Child

Lower age limit

12 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

800

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)

Sponsor details
Marijana 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)

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	01/05/2010		Yes	No