

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

<b>Submission date</b> 29/01/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/04/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/05/2010	<b>Condition category</b> 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

**Contact name**  
Dr Iva Hojsak

**Contact details**  
Children's Hospital Zagreb  
Klaiceva 16  
Zagreb  
Croatia  
10000  
ivahojsak@gmail.com

## Additional identifiers

**Protocol serial number**  
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 (10<sup>6</sup> to 10<sup>9</sup> 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

## **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 informed consent will be randomly assigned into one of the two following groups:

Group A: Children will receive *Lactobacillus GG* at a dose 10<sup>10</sup> 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 bronchiolitis (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?
<a href="#">Results article</a>	results	01/05/2010		Yes	No