

Lactobacillus GG in prevention of gastrointestinal and respiratory tract infections in healthy 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 02/12/2010	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

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 (10^6 to 10^9 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, Klaićeva 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

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Gastrointestinal and respiratory tract infections in children

Interventions

All children at kindergarten whose parents have signed an informed 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(s)

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 bronchiolitis (diagnosis by physician)
4. Duration of gastrointestinal and respiratory tract infections

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

12 months

Upper age limit

7 years

Sex

All

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)

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

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