

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

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| 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

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 (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

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 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 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 bronchiolitis (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 |