Effect of Probiotics in Reducing Infections and Allergies in Young Children Starting Daycare (ProbiComp)

ClinicalTrials.gov Identifier: NCT02180581

Recruitment Status : Completed
First Posted : July 2, 2014
Last Update Posted : August 24, 2016

Sponsor:
University of Copenhagen

Collaborators:
The Danish Council for Strategic Research
Chr Hansen
Technical University of Denmark
University of Bergen
Odense University Hospital
Statens Serum Institut

Information provided by (Responsible Party):
Arne Astrup, University of Copenhagen

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How to Read a Study Record

Study Description

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Brief Summary:

The aim of the intervention is to examine the effect of a combination of the two bacterial strains BB-12 and LGG, provided for 6 month, on the prevalence of infections and allergic manifestations in small children, and how a combination of BB-12 and LGG affects the immune system, gastrointestinal tract and the microbiota. Children are enrolled during 2 winter seasons.

Condition or disease	Intervention/treatment
Days Absent From Daycare Respiratory Tract Infections Gastrointestinal Infections Allergy	Dietary Supplement: Probiotic (2 * 10^9 cfu/day) Dietary Supplement: Placebo

Study Design

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Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	290 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:	Prevention
Official Title:	Effect of Probiotics in Reducing Infections and Allergies in Young Children Starting Daycare
Study Start Date :	August 2014
Primary Completion Date :	June 2016
Study Completion Date :	June 2016

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Allergy

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Probiotic (2 * 10^9 cfu/d) Daily intake of bifidobacterium animalis ssp. Lactis (BB12) and Lactobacillus Rhamnosus GG (LGG) in a dosage of 10^9 cfu/day of each strain. The probiotics are provided as powder in a sachet, and can be added to food or drink	Dietary Supplement: Probiotic (2 * 10^9 cfu/day) Combination of two probiotics (2 * 10^9 cfu/day) or probiotics for 6 months Other Names: • bifidobacterium animalis ssp. Lactis (BB12), 10^9 cfu/day • Lactobacillus Rhamnosus GG (LGG), 10^9 cfu/day
Placebo Comparator: Placebo provided as powder in a sachet, and can be added to food or drink	Dietary Supplement: Placebo Placebo for 6 months

Outcome Measures

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Primary Outcome Measures :

1. Number of days absent from daycare due to respiratory and gastrointestinal infections [Time Frame: up to 6 month]

   Recorded weekly by the parents using web-based questionnaires

Secondary Outcome Measures :

1. Acute upper respiratory tract infections [Time Frame: Up to 6 month]

   Number of days with acute upper respiratory tract infections (URTI); Number of children with at least 1 episode of URTI; Number of children with at least 3 episodes of URTI; Number of URTI episodes/child/year; Duration of URTI episodes (days);

   Additionally,symptoms of cold (defined as 2 days with runny/stuffy nose or cough)

   Recorded by the parents daily/weekly using web-based questionnaires.

2. Acute lower respiratory infections [Time Frame: Up to 6 month]

Number of children with at least 1 episode of a lower respiratory tract infection (LRTI).

LRTI include bronchitis and pneumonia

Recorded by the parents weekly using web-based questionnaires.

3. Gastrointestinal infections [Time Frame: Up to 6 month]

Number of children with at least 1 episode of diarrhea; Duration of episodes with diarrhea(days); Number of episodes/child/year with diarrhea; Number of days with vomiting.

Recorded by the parents daily using web-based questionnaires

4. Fever [Time Frame: Up to 6 month]

Number of days with fever

Recorded by the parents using web-based questionnaires

5. Antibiotic use [Time Frame: Up to 6 month]

Number of treatments with antibiotics during the intervention period

Recorded weekly by the parents using web-based questionnaires

6. Allergies [Time Frame: Up to 6 month]

Number of children developing allergies during the intervention period (asthma, allergic rhinitis, atopic dermatitis, food allergies); Age for diagnosis of allergies; Use of medication due to allergies.

Recorded by the parents using web-based questionnaires

7. Absence from day care due to illness other than infections [Time Frame: Up to 6 month]

Number of days the child is absent from day care due to illness, which is not due to infections.

Recorded by the parents weekly using web-based questionnaires

8. Parental absence from work due to illness of the child [Time Frame: Up to 6 month]

Number of days a parent is absent from work due to illness of the child (infections and other illnesses, respectively)

Recorded by the parents weekly using web-based questionnaires

9. Medical visits [Time Frame: Up to 6 month]

   Number of visits to a doctor due to infections and other illnesses, respectively.

   Recorded by the parents using web-based questionnaires

10. Change from baseline in Thymus size [Time Frame: At baseline and after 6 mo (end of intervention)]

    Change in thymic size during intervention period will be evaluated using ultrasound

Other Outcome Measures:

1. Change from baseline in biological markers for the immune system [Time Frame: At baseline and after 6 mo]

   Analysis of biological material investigating the effect on the immune system by biological markers .

2. Change from baseline in biological markers for gastro-intestinal tract [Time Frame: At baseline and after 6 mo]

   Analysis of biological material investigating the effect on the gastrointestinal tract.

3. Change from baseline in Biological markers of allergy [Time Frame: At baseline and after 6 mo]

   analysis of biological samples investigating the effect on allergy by biological markers at baseline and at 6 mo

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research

staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	8 Months to 14 Months (Child)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

- Expected to start daycare between the age of 8-14 month
- Intervention start 0 days to 12 weeks before starting daycare
- Expected to start daycare from september to february (both month included)
- Single born

Exclusion Criteria:

- Exclusion Criteria:
- Children born before 37th gestational week
- Children with a birth weight < 2500 g
- Children suffering from severe chronic illness
- Children receiving regular medication
- Children who have received antibiotics within a month before intervention start
- Children whose parents do not speak Danish

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02180581***

Locations

Denmark

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Sponsors and Collaborators

University of Copenhagen

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Technical University of Denmark

University of Bergen

Odense University Hospital

Statens Serum Institut

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Responsible Party:	Arne Astrup, Professor, University of Copenhagen
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Infections
Allergy
Immune function
Microbiota
Infant

Additional relevant MeSH terms:

Infection	Respiratory Tract Infections
Communicable Diseases	Immune System Diseases
Hypersensitivity	Respiratory Tract Diseases