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Probiotics and vitamin C for the management of upper respiratory tract infections

Submission date 11/09/2019	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 16/10/2019	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 18/11/2024	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Upper respiratory tract infections (URTI) in children, which include the common cold and coughs, present a considerable healthcare burden involving not only the cost of direct medical care but also that incurred due to parental absence from work to look after sick children. Antibiotics are often used inappropriately for the treatment of these infections, leading to the development of bacterial resistance. In the pilot PROCHILD study (ISRCTN28722693), supplementation with the Lab4 probiotic consortium and vitamin C showed a significant reduction in the incidence rate and number of days with URTI symptoms in preschool children aged 3-6 years. The aim of this study is to extend these findings to children attending preschool facilities and primary school.

Who can participate?
Children who attend preschool (3-6 years old) or Stage 1 of primary school (1st-4th grade; 7-10 years old)

What does the study involve?
Children will be randomly allocated to take daily either one chewable tablet of probiotics in combination with vitamin C or a placebo (dummy) for 6 months. The parents/guardians of the children and the research team will be unaware of who is taking what. At the start of the study, the children will be examined by a paediatric physician and background information (age, BMI, history of allergy, regular medication) will be recorded. Parents/guardians will need to complete a diet habit and physical activity pattern questionnaire at the beginning of the study and upon completion. During the 6-month study period, the parents/guardians will complete daily health diaries including the children's antibiotic use and any absence from preschool/primary school. The children will be examined by a paediatric physician at prescheduled 2, 4 and 6-month appointments or during unscheduled visits. Stool samples will be collected on a voluntary basis at the start and end of the study.

What are the possible benefits and risks of participating?
Supplementation with a probiotic and vitamin C combination may be beneficial in the management of upper respiratory tract infections. There were no adverse reactions associated with the active intervention in the previous PROCHILD study (ISRCTN28722693). The active and placebo tablets have been tested for the absence of Coliforms, Salmonella, yeasts and moulds

and heavy metals at an independent testing laboratory (EUROFINS BEL/NOVAMANN s.r.o, Nove Zamky, Slovakia).

Where is the study run from?
Institute of Medical Chemistry, Biochemistry and Clinical Biochemistry, Comenius University, Bratislava, Slovakia

When is the study starting and how long is it expected to run for?
December 2016 to December 2018

Who is funding the study?
Cultech Ltd., Port Talbot, UK

Who is the main contact?
Associate Professor Jana Muchova, PhD
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
RPv1.2D

Study information

Scientific Title
An investigation of the efficacy of long term consumption of a probiotic and vitamin C combination on the prevention of upper respiratory tract infections in children attending preschool or primary school

Acronym
PROCHILD-2

Study objectives
Long-term supplementation with Lab4 probiotic and vitamin C combination would be beneficial in the management of upper respiratory infections in children attending pre-school or Stage 1 (1st -4th grade) of primary school

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/11/2016 Ethics committee of Bratislava self-governing region (Sabinovská 16, PO Box 106, 82005 Bratislava, Slovakia; Tel: +421 (0)2 48264912; Email: ivana.vanacka@region-bsk.sk), ref: 07878/2016-HF

Primary study design
Interventional

Study design
Multicentre randomised double-blind placebo-controlled study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Respiratory tract infections in children

Interventions
Eligible subjects will be allocated in a 1:1 ratio to the two arms of the study according to a computer-generated random sequence using block randomisation with a block-size of four and stratified by centre. The randomisation will be performed by the statistician, who will have no contact with the participants. Participants will be enrolled and assigned sequentially to interventions by the paediatric physicians. The research team and parents/guardians will be unaware of the group assignments.

Participants randomised to active or placebo group will be required to take one chewable tablet per day for 6 months:
1. Active intervention contains the Lab4 probiotic consortium (Lactobacillus acidophilus CUL60, Lactobacillus acidophilus CUL21, Bifidobacterium bifidum CUL20 and Bifidobacterium animalis subsp. lactis CUL34) at a total of 12.5 billion cfu and 50 mg vitamin C per tablet.
2. The placebo intervention contains the same ingredients without the probiotic consortium and Vitamin C actives and is identical in appearance to the active intervention.

Intervention Type
Supplement

Primary outcome(s)
The incidence and duration of URTI assessed using daily health diaries completed by parents /guardians over the six month study period

Key secondary outcome(s)
Over the six month study period:
1. Absence from preschool or primary school assessed using the daily health diaries completed by parents/guardians
2. Antibiotic prescriptions assessed using the daily health diaries completed by parents /guardians and paediatric physician's records
3. Lower respiratory tract infections assessed using the paediatric physician's records
4. Gastrointestinal symptoms, such as change in bowel habits, vomiting, stomach ache, assessed using the daily health diaries completed by parents/guardians
5. Microbiota composition, diversity and functionality assessed using next-generation sequencing, traditional culture methods and 1H NMR spectroscopic analysis. The faecal sample collection is from a single centre and on a voluntary basis at day 0 (baseline) and 6 months

Completion date
01/10/2018

Eligibility

Key inclusion criteria
1. Healthy children of either sex attending preschool facilities (3-6 years old) or primary school (7-10 years old)
2. Children with no flu vaccination
3. Parents/guardian who are willing to give written informed consent
4. Children who are willing to avoid any other probiotic supplements or dairy probiotic products (probiotic yoghurt, acidophilus milk, kefir etc.) for the duration of the project
5. Provision of faecal sample at the beginning and the end of the study will be voluntary

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Years

Upper age limit
10 Years

Sex
All

Key exclusion criteria
1. Parents are unable/unwilling to give written informed consent
2. Taking regularly any dairy probiotic product (probiotic yoghurt, acidophilus milk, kefir, etc)
3. Taking regularly any probiotic and prebiotic supplements
4. Taking medication to stimulate the immune system

5. Taking regularly Vitamin C
6. Sensitive to xylitol/sorbitol

Date of first enrolment
15/12/2016

Date of final enrolment
29/03/2018

Locations

Countries of recruitment
Slovakia

Study participating centre
JuvenaliaA, s.r.o, Children’s Health Centre, Dunajska Streda, Slovakia
Veľkoblahovská 23
Dunajská Streda
Slovakia
92901

Study participating centre
Children and adolescents health practice, DFNsP, Bratislava, Slovakia
Limbová 1
Bratislava
Slovakia
83340

Study participating centre
Meditrix s.r.o., Bratislava, Slovakia
Ružinovská 10
Bratislava
Slovakia
82007

Study participating centre
GAMI-med, s.r.o, General Practice for children and adolescents, Bratislava, Slovakia
Šustekova 2
Bratislava
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85104

Sponsor information

Organisation
Cultech Ltd

ROR
https://ror.org/00555bk04

Funder(s)

Funder type
Industry

Funder Name
Cultech Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		01/12/2023	18/11/2024	Yes	No