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PROCHILD: Probiotics in prevention of respiratory tract infections

Submission date	Recruitment status	[ ] Prospectively registered
11/11/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/04/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/04/2011	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RPv1.0

Study information

Scientific Title
The influence of long term consumption of probiotics and vitamin C combination on infections in children attending preschool facilities

Acronym
PROCHILD

Study objectives
This study aims to investigate whether combination of probiotics and vitamin C prevents the incidence, duration and severity of upper and lower respiratory infections in children attending preschool facilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical committee of Trnava self-governing region, Trnava, Slovakia approved on the 16th of September 2010

Study design
Randomised double blind placebo controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details below to request a Parental Information Sheet

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

Interventions
Participants randomised to active or placebo group will be required to take one chewable tablet per day for 6 months.
1. Active intervention: Probiotics consisting of a combination of 4 strains; L. acidophilus CUL-60,

L. acidophilus CUL-21, B. bifidum CUL-20 and B. lactis CUL-34 at a total of 1.25x10^10 cfu per tablet and 50 mg vitamin C and xylitol (base ingredient) per tablet
2. Placebo: Xylitol

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Incidence, duration and severity of upper and lower respiratory tract infections and gastrointestinal infections.
Symptom Diary is collected on weekly basis.

Secondary outcome measures
1. Changes in key immunological parameters and markers of oxidative stress
2. Changes in levels of sIgA and cortisol
Blood, saliva and urine samples are collected at baseline and 6 months.

Overall study start date
01/10/2010

Completion date
30/11/2011

Eligibility

Key inclusion criteria
1. Children aged 4 to 6 years old of either sex
2. Parental/guardian written informed consent and completed confidential health status to be obtained for all children participating

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Participants whose parents are unable/unwilling to give written informed consent
2. Participants who are not prepared to provide blood, urine and saliva samples as required
3. Participants who are taking the products/medications for the stimulation of immune system (â glucans), isoprinosine (methisoprinolum), ribomunyl, immunomodulants (lysate of bacteria)
4. Participants who are taking regularly daily any dairy probiotic product (yoghurt with biocultures, Acidophilus milk, kefir, etc), probiotic supplements
5. Participants sensitive to xylitol/sorbitol

Date of first enrolment
01/10/2010

Date of final enrolment
30/11/2011

Locations

Countries of recruitment
Slovakia

Study participating centre
Institute of Medical Chemistry, Biochemistry and Clinical Biochemistry
Bratislava
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813 72

Sponsor information

Organisation
Cultech Ltd (UK)

Sponsor details
c/o Dr Nigel Plummer
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United Kingdom
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Sponsor type
Industry

ROR
https://ror.org/00555bk04

Funder(s)

Funder type
Industry

Funder Name
Cultech Ltd (UK)

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