

PROCHILD: Probiotics in prevention of respiratory tract infections

Submission date 11/11/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/04/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/04/2011	Condition category Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Zdenka Durackova

Contact details
Institute of Medical Chemistry, Biochemistry and Clinical Biochemistry
Medical School
Comenius University
Sasinkova 2
Bratislava
Slovakia
813 72
+421 (0)2 5935 7416
zdenka.durackova@fmed.uniba.sk

Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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 1.25×10^{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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 years

Upper age limit

6 years

Sex

All

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 (β 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

Slovakia

813 72

Sponsor information

Organisation

Cultech Ltd (UK)

ROR

<https://ror.org/00555bk04>

Funder(s)

Funder type

Industry

Funder Name

Cultech Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration