

# PROCHILD: Probiotics in prevention of respiratory tract infections

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

**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

**Primary study design**

Interventional

**Study design**

Randomised double blind placebo controlled pilot study

**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  $1.25 \times 10^{10}$  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 (α 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