

# PROCHILD: Probiotics in prevention of respiratory tract infections

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

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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  $1.25 \times 10^{10}$  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 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 (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)

### **Sponsor details**

c/o Dr Nigel Plummer

Unit 3 Christchurch Road

Baglan Industrial Park

Port Talbot

United Kingdom

SA12 7BZ

### **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