

# Effect of probiotics following antibiotic therapy

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<b>Registration date</b> 07/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/07/2015	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The human gut has been identified as one of the parts of the body that is most densely populated with bacteria (known collectively as the gut microbiota). Antibiotics are used to combat infections caused by harmful (pathogenic) bacteria. However, antibiotics can have a damaging effect on the gut microbiota and can lead to the development of bacteria that are resistant to antibiotics. Probiotics are live bacteria and yeasts that may be good for your health. This study will assess the effects of taking probiotics when taking antibiotics on the composition of the gut microbiota and whether there are any changes in the incidence of antibiotic-resistant organisms.

### Who can participate?

Children aged 3-18 years with infections requiring antibiotic treatment.

### What does the study involve?

Participants will be randomly allocated to take either probiotics or placebo (dummy) tablets for 30 days and provide stool, urine and saliva samples at the start of the study, upon completion of the antibiotic course and after 30 days (at the end of the study). Parents/guardians will need to complete a diet and physical activity questionnaire at the start and end of the study and also record children's weekly health diaries.

### What are the possible benefits and risks of participating?

Probiotic supplementation is intended to prevent disruption of the gut microbiota. There are no known risks to participants taking part in this study.

### Where is the study run from?

Children's Health Centre Juvenalia Ltd, Dunajska Streda, Slovakia.  
Institute of Medical Chemistry, Comenius University, Bratislava, Slovakia.

### When is the study starting and how long is it expected to run for?

From November 2014 to December 2015.

### Who is funding the study?

Cultech Ltd, Port Talbot, UK.

Who is the main contact?  
Associate Professor Jana Muchova.  
jana.muchova@fmed.uniba.sk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Jana Muchova

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**Contact details**  
Institute of Medical Chemistry, Biochemistry and Clinical Biochemistry  
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81372

## Additional identifiers

**Protocol serial number**  
PPv1.0

## Study information

**Scientific Title**  
A study to Investigate the impact of probiotics on children's gut microbiota following antibiotic therapy

**Acronym**  
PROCHANT

**Study objectives**  
This study aims to investigate the impact of supplementation with Lab4 probiotics on the gut microbiota of 3 to 18 year olds when administered in conjunction with antibiotic therapy.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Ethical committee of Trnava Self-Governing Region, 22/01/2015

**Study design**  
Randomised double-blind placebo-controlled single-centre study

## Primary study design

Interventional

## Study type(s)

Other

## Health condition(s) or problem(s) studied

Oral antibiotic therapy

## Interventions

Participants randomised to active or placebo group will take study products orally once daily for 30 days:

1. The active will contain Lab4 probiotic consortium (Lactobacillus acidophilus CUL60, Lactobacillus acidophilus CUL21, Bifidobacterium bifidum CUL20 and Bifidobacterium animalis subsp. lactis CUL34) at  $2.5 \times 10^{10}$  CFU per day

2. The placebo control will be an identical looking tablet containing maltodextrin

Both interventions will be prepared by Cultech Ltd, Port Talbot, UK

## Intervention Type

Supplement

## Primary outcome(s)

1. Changes in the composition and diversity of gut microbiota

2. Changes in metabonomic profiles. Stool and urine samples to be taken within 24 hours of first antibiotic dose, on the day of last antibiotic dose and on last day of active or placebo intervention dose at day 30

## Key secondary outcome(s)

1. Impact of probiotics on wellbeing (changes in bowel habits, blood pressure, etc)

2. Changes in composition and diversity of oral microbiota

3. Stool and saliva samples at baseline, completion of antibiotic course and upon completion of the probiotic or placebo intervention at day 30

## Completion date

18/12/2015

## Eligibility

### Key inclusion criteria

1. Children aged 3 to 18 years old of either sex with infections requiring treatment by one of the following classes of antibiotics: cephalosporins; clarithromycin and amoxicillins/clavulanic acids

2. Participants willing to provide saliva, urine and stool samples

3. Parents/guardians willing to give written informed consent and information on children's daily bowel habits

### Participant type(s)

Patient

### Healthy volunteers allowed

No

**Age group**

Child

**Lower age limit**

3 years

**Upper age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Participants whose parents are unable/unwilling to give written formal consent
2. Participants not prepared to provide saliva, urine and stool samples
3. Participants who took antibiotics in the 4 weeks prior to enrolment
4. Participants sensitive to xylitol or sorbitol

**Date of first enrolment**

09/03/2015

**Date of final enrolment**

30/10/2015

**Locations****Countries of recruitment**

Slovakia

**Study participating centre**

Children's Health Centre Juvenalia Ltd

NsP, Velkoblahovska 23

Dunajska Streda

Slovakia

92901

**Sponsor information****Organisation**

Cultech Ltd

**ROR**

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

## **Funder(s)**

### **Funder type**

Not defined

### **Funder Name**

Cultech Ltd (UK)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

#### **IPD sharing plan summary**

Not expected to be made available