

# Can taking probiotics ('friendly' bacteria) reduce upper respiratory tract infections in healthcare workers?

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<b>Registration date</b> 02/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/05/2020	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Probiotics are 'friendly bacteria' that can have beneficial effects by, amongst other ways, interacting with the bacteria that already live in the gut to promote a healthy gut microbiota that supports the well-being of the host. The aim of this study is to see if the daily consumption of a probiotic supplement will modulate the functioning of the gut microbiota resulting in the reduced incidence and/or duration of Upper Respiratory Tract Infection (URTI, also known as the common cold), and improve quality of life and wellbeing in healthcare workers (who are prone to infections from exposure to "unwell individuals").

### Who can participate?

Adults aged between 18 to 70 years working in a healthcare setting i.e. nurse, doctor, pharmacist, health-care porter.

### What does the study involve?

Participants will be asked to take one capsule containing either the active product (probiotic) or an identical inactive product (placebo) every day for 4 months (112 days). There is an equal chance that the participant will be assigned to take the active or placebo and neither the participant themselves nor the study researchers will know who is taking what.

Participants complete a daily diary indicating if they are experiencing any cold-like symptoms (coughing, sneezing and blocked nose). Participants will complete a questionnaire assessing the general quality of life, well-being and health at 0, 2 and 4 months. Blood pressure, body weight and peak flow (how well your lungs are functioning) will be measured at the start and end of the study. Blood and saliva samples at 0 and 4 months and from volunteers, stool (faecal) and urine samples at 0 and 4 months.

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

It is hoped that the results from this work will lead to improvements in our understanding of the benefits of taking probiotics and those participants receiving the probiotic might experience reduced symptoms.

There have been no adverse reactions associated with the consumption of Lab4 probiotics. but mild side effects such as a change in bowel habit and/or increased flatulence may occur during the first few days of taking the supplement.

Where is the study run from?

The University Clinic of Pulmonology and Allergology, Saints Cyril and Methodius University of Skopje (Macedonia)

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

December 2017 until April 2018

Who is funding the study?

Cultech Ltd (UK)

Who is the main contact?

Dr Sue Plummer, [suep@cultech.co.uk](mailto:suep@cultech.co.uk)

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

PROBINS 8.1

# Study information

## Scientific Title

PROBiotics for the prevention of Upper Respiratory Tract INfectionS in healthcare workers

## Acronym

PROBINS

## Study objectives

Daily supplementation with Lab4 probiotics will reduce the incidence and/or duration of Upper Respiratory Tract Infections (URTI) and improve quality of life and general wellbeing in health care workers.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 20/02/2017, Ethics Committee for Clinical and Other Investigations related to Medicines and Medical Supplies within the Agency for Medicines and Medical Supplies of the Republic of Macedonia (St. Styril and Methodius 6g.S4 floor: t, Skopje, Macedonia; +389 (0)2 5112 394; email not available), ref: 11-372/1

## Study design

Single-centre randomised double-blind placebo-controlled parallel-group study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Community

## Study type(s)

Prevention

## Participant information sheet

Not available in web format, please use contact details to request participant information sheet

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

Upper respiratory tract infection

## Interventions

The active product: a capsule containing the Lab4 probiotic consortium (Lactobacillus acidophilus CUL-60 (NCIMB 30157), Lactobacillus acidophilus CUL-21 (NCIMB 30156), Bifidobacterium bifidum CUL-20 (NCIMB 30153) and Bifidobacterium animalis subsp lactis CUL-34 (NCIMB 30172)) at a total of  $5 \times 10^{10}$  (50 billion) colony forming units (cfus) per day. The placebo: an identical looking capsule containing microcrystalline cellulose and maltodextrin.

Trial subjects were allocated in a 1:1 ratio into two parallel study arms (active arm or placebo arm) according to a randomisation protocol provided by an independent statistician. The intervention period was 16 weeks (112 days).

### **Intervention Type**

Supplement

### **Primary outcome measure**

Incidence and duration of URTI symptoms (Patient records at 4 months)

### **Secondary outcome measures**

1. Incidence and duration of absence from work, antibiotic usage and visits to general practitioners (Daily records)
2. General well-being and health assessed (Quality of life questionnaire; 0, 2, 4 months)
3. Microbiota composition/functionality. (Traditional and NGS; 0, 4 months)
4. Bodyweight, blood pressure and peak flow (0, 2, 4 months)
5. Analysis of biomarkers in blood/urine/saliva (0, 4 months)\*

\*The methods of analysis for blood/urine/saliva have yet to be finalised

### **Overall study start date**

10/01/2017

### **Completion date**

12/04/2018

## **Eligibility**

### **Key inclusion criteria**

1. Male or Female aged between 18 and 70 years
2. Must work in a health-care setting

### **Participant type(s)**

Healthy volunteer

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

104

### **Total final enrolment**

104

### **Key exclusion criteria**

1. Unable to give written informed consent
2. Not prepared to provide blood and saliva samples as required
3. Taking the products/medications that stimulate immune function/inflammation. For example:  $\beta$  glucans, isoprinosine (methisoprinolum), ribomunyl, immunomodulators lysate of bacteria
4. Have taken probiotic supplements within 2 weeks of trial start
5. Pregnant or lactating
6. Received oral antibiotics within 3 weeks of trial start

**Date of first enrolment**

05/12/2017

**Date of final enrolment**

22/12/2017

## **Locations**

**Countries of recruitment**

North Macedonia

**Study participating centre****Saints Cyril and Methodius University of Skopje**

The University Clinic of Pulmonology and Allergology

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Skopje

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1000

## **Sponsor information**

**Organisation**

Cultech (United Kingdom)

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**Sponsor type**

Industry

**Website**

<http://www.cultech.co.uk/>

**ROR**

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

## Funder(s)

**Funder type**

Industry

**Funder Name**

Cultech Ltd

## Results and Publications

**Publication and dissemination plan**

Results will be published in a peer-reviewed scientific journal.

**Intention to publish date**

31/12/2020

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

The current data sharing plans for this study are unknown and will be available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			15/05/2020	No	No