

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

Submission date 30/03/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 02/04/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/05/2020	Condition category 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

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Prevention

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 5×10^{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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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: β 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

North Macedonia

1000

Sponsor information

Organisation

Cultech (United Kingdom)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Cultech Ltd

Results and Publications

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?
Protocol file			15/05/2020	No	No

