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

Submission date 30/03/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 02/04/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/05/2020	**Condition category** Respiratory	[_] Individual participant data [_] 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

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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 x 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: 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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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?
Protocol file			15/05/2020	No	No