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Effect of probiotics following antibiotic therapy

Submission date	Recruitment status	[_] Prospectively registered
25/06/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/07/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/07/2015	Infections and Infestations	[_] 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.
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Contact information

Type(s)
Scientific

Contact name
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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

Primary study design
Interventional

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

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 2.5x10^10 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 amoxicllins/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