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Effect of probiotic supplement (L. plantarum strain TENSIA) on healthy volunteers

Submission date	Recruitment status	[X] Prospectively registered
09/08/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/08/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/02/2022	Digestive System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Probiotics are live bacteria and yeasts promoted as having various health benefits. Probiotic products include food products such as yoghurt and dietary supplements in capsule, powder or liquid form. Centuries-long use of lactic acid bacteria in the food industry has proven their safety. Nevertheless, it is important to test the safety of each potential probiotic. The aim of this study is to assess the safety of a probiotic food supplement, the survival of the probiotic bacteria in the gut, and its effect on the gut bacteria.

Who can participate?
Healthy volunteers aged 18 and over

What does the study involve?
Participants are randomly allocated to take either the probiotic supplement or a placebo (dummy supplement). They are asked to fill in a questionnaire assessing any digestive symptoms (stomach pain, flatulence, bloating, and stool frequency) once a week and to provide blood, urine and fecal samples to test the effect of the probiotic supplement on the human body.

What are the possible benefits and risks of participating?
All participants receive an assessment of their health status and if necessary, a consultation with a nutritionist. The study causes minimal inconvenience to participants. As blood samples are taken by an experienced nurse, the procedure is safe. However, there may be bruising and discomfort at the site of the blood test as with any blood test. The amounts of blood we are taking are small enough that they should not make participants feel fatigue or cause anemia. There may be local red reactions at the site of the injections.

Where is the study run from?
Centre for Clinical and Physiological Research of BioCC OÜ (Estonia)

When is the study starting and how long is it expected to run for?
September to November 2011

Who is funding the study?
BioCC OÜ (Estonia)

Who is the main contact?
Dr Pirje Hütt
pirje.hutt@ut.ee

Contact information

Type(s)
Scientific

Contact name
Prof Marika MIkelsaar

Contact details
University of Tartu
Faculty of Medicine
Dept of Microbiology
Ravila 19
Tartu
Estonia
50411
+372 (0)737 4173
marika.mikelsaar@ut.ee

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
205T-5

Study information

Scientific Title
Effect of a food supplement containing the probiotic strain of Lactobacillus plantarum TENSIA DSM 21380 on blood indices and intestinal microflora of healthy volunteers: a randomized placebo-controlled parallel trial

Acronym
TE 7

Study objectives
The consumption of probiotic dietary supplement containing L. plantarum strain TENSIA is safe:
1. No adverse gastrointestinal effects (i.e. no abdominal discomfort like abdominal pain,

flatulence or bloating,
2. No negative shifts in values of systemic inflammation markers
3. No allergic sensibilisation
4. No harm to essential organs
5. No unwanted changes in the glucose content in blood serum or in lipid metabolism

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Review Committee on Human Research of the University of Tartu, 13/06/2011, ref: 205T-5

Study design
Randomized placebo-controlled parallel trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Improving intestinal flora

Interventions
Participants randomised to active or placebo group will be required during 3 weeks:
1. Active intervention: probiotic supplement containing Lactobacillus plantarum strain TENSIA (daily dose: 3x10/10 colony forming units [CFU])
2. Placebo group: maltodextrin 100 mg

Intervention Type
Supplement

Phase
Phase I

Drug/device/biological/vaccine name(s)
L. plantarum strain TENSIA supplement

Primary outcome measure

1. Adverse gastrointestinal effects
2. Negative shifts in values of systemic inflammation markers
3. Changes in lipid metabolism
4. Changes in key immunological parameters and markers of oxidative stress
5. Reduction of blood pressure
Measured pre intervention, at the end of the intervention and also 1 week post intervention

Secondary outcome measures
1. Changes in fecal microflora
2. Persistence of ingested probiotic strain for 1 week

Overall study start date
26/09/2011

Completion date
14/11/2011

Eligibility

Key inclusion criteria
1. Wish to participate in the study
2. Aged 18 years and over
3. Healthy (i.e., no known health problems and no medical conditions that require drug therapy)
4. Signed informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50, 25 subjects in each arm

Key exclusion criteria
1. History of any gastrointestinal disease
2. Use of any antimicrobial drug within last month
3. Use of any regular concomitant medication, including medical preparations
4. Food allergy
5. Pregnancy or breastfeeding

Date of first enrolment
26/09/2011

Date of final enrolment
14/11/2011

Locations

Countries of recruitment
Estonia

Study participating centre
University of Tartu
Tartu
Estonia
50411

Sponsor information

Organisation
BioCC OÜ

Sponsor details
Kreutzwaldi 1
51014
Tartu
Estonia
51014
+372 (0) 516 4210
ene.tammsaar@tptak.ee

Sponsor type
Industry

Website
http://www.tptak.ee

Funder(s)

Funder type
Industry

Funder Name
Bio-Competence Centre of Healthy Dairy Products LLC (Estonia)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration