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Effect of different doses of L. planatrum TENSIA containing probiotic cheese on clinical parameters of volunteers

Submission date	Recruitment status	[X] Prospectively registered
10/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/03/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/03/2010	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
190T-10 from 22.02.2010

Study information

Scientific Title
Effect of different doses of L. planatrum TENSIA containing probiotic cheese on blood indices and intestinal microflora of healthy adult volunteers: An open label, interventional study

Acronym
TE 5

Study objectives
1. The consumption of a probiotic Lactobacillus plantarum strain containing cheese in daily (high) dose of 100g (probiotic dose being 10^11 CFU)
1.1. is safe: no negative gastrointestinal effect, no elevated total cholesterol and no negative shifts in cholesterol fractions
1.2. affects positively the functions of the cardio-vascular system of human body.

2. The consumption of a probiotic Lactobacillus plantarum strain containing cheese in daily (low) dose of 100g (probiotic dose being 10^5 Colony Forming Units [CFU]) has positive impact on blood indices of healthy volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Review Committee on Human Research of the University of Tartu approved on the 22nd of February 2010 (ref: 190T-10)

Study design
Open interventional dose safety study

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 contact Dr Pirje Hütt [pirje.hutt@ut.ee] to request a patient information sheet (in Estonian)

Health condition(s) or problem(s) studied
blood indices and intestinal microflora

Interventions

Probiotic cheese consumption
Group I of volunteers 100 g probiotic cheese once a day for 3 weeks in a daily dose of probitoic being 10^5 CFU
Group II of volunteers 100 g probiotic cheese once a day for 3 weeks in a daily dose of probitoic being 10^11 CFU
Blood, urine and faecal samples are collected at the recruitment, and after 3 weeks of probiotic treatment

Samples of fasting blood, fecal and urine samples will be collected at recruitment and at the end of the trial after administration of the L. plantarum TENSIA comprising cheese.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The health indices of study participants are assessed at the recruitment and after 3 weeks of probiotic treatment.
1.1. Height
1.2. Weight
1.3. Body mass index (BMI)
1.4. Blood pressure
2. The self-reported questionnaire is applied containing questions on welfare, and habitual gastrointestinal symptoms (abdominal pain, flatulence, bloating, and stool frequency), is filled once a week during the trial
3. Haematological indices will be determined at the recruitment and after 3 weeks of probiotic treatment. by standard laboratory methods using certified assays in the local clinical laboratory (United Laboratories of Tartu University Clinics, Estonia).
3.1. Haemoglobin
3.2. White blood cell count
3.3. Red blood cells count
3.4. Platelet count
4. Routine biochemical indices will be determined at the recruitment and after 3 weeks of probiotic treatment
4.1. Albumin
4.2. Ferritine
4.3. Plasma glucose
4.4. High-sensitive CRP (hs-CRP)
4.5. Total cholesterol
4.6. LDL-cholesterol (LDL)
4.7. HDL-cholesterol (HDL)
4.8. Triglycerides
4.9. Serum creatinine
4.10. Alanine transaminase (ALAT)
4.11. Aspartate transaminase (ASAT)
4.12. Immunoglobulin IgE levels
5. Safety of high doses of TENSIA

Secondary outcome measures

Positive impact on human health

Overall study start date
10/05/2010

Completion date
14/06/2010

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 recruited from GP clinics, divided into in two groups

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
10/05/2010

Date of final enrolment
14/06/2010

Locations

Countries of recruitment
Estonia

Study participating centre
Ravila str 19
Tartu
Estonia
50411

Sponsor information

Organisation
Bio-Competence Centre of Healthy Dairy Products Ltd (Estonia)

Sponsor details
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Sponsor type
Industry

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ROR
https://ror.org/02e801388

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration