

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

Submission date 10/03/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/03/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/03/2010	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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. plantarum 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 probiotic being 10^5 CFU

Group II of volunteers 100 g probiotic cheese once a day for 3 weeks in a daily dose of probiotic 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. Ferritin

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

Website

<http://www.tptak.ee>

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