# 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

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### 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