ISRCTN29040130 https://doi.org/10.1186/ISRCTN29040130

Effect of the probiotic cheese on high-normal blood pressure

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	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
High blood pressure (hypertension) is a major cardiovascular (heart disease) risk factor. It has been shown that reducing blood pressure reduces the risk of cardiovascular diseases and stroke. For people with high-normal blood pressure and without any serious risk factors like diabetes and kidney failure clinical treatment using medications is not indicated, but changes in lifestyle and diet could be helpful. The purpose of this study is to assess the safety of a probiotic Edam-type cheese and its effectiveness on blood pressure reduction.

Who can participate?
Generally healthy persons aged 18 years and over with elevated blood pressure who do not take medications will be recruited through clinics in Southern and Central Estonia.

What does the study involve?
Participants are randomly allocated to eat 50 g per day of either probiotic cheese or normal cheese, or to receive no treatment. The study duration is 4 weeks, and participants are asked to assess their well-being and gastrointestinal (digestive) effects, and also to provide blood, urine and fecal samples to test the effects of the probiotic.

What are the possible benefits and risks of participating?
Study participants will receive an assessment of their health status and if necessary, a consultation with a nutritionist and/or a specialist. 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 you feel fatigue or cause anemia. There may be local red reactions at the site of the injections.

Where is the study run from?
The study is carried out in a cooperation between the Bio-Competence Centre of Healthy Dairy Products LLC, the Faculty of Medicine, University of Tartu and the Dairy Cooperative E-piim (Estonia). The study takes place at the Centre for Clinical and Physiological Research of the Bio-Competence Centre of Healthy Dairy Products LLC in Tartu, Estonia.

When is the study starting and how long is it expected to run for?
Patients will be enrolled in the study in September 2011. Follow-up examinations will continue until December 2011.

Who is funding the study?
Bio-Competence Centre of Healthy Dairy Products LLC, the EU Structural Funds.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
202M-25

Study information

Scientific Title
Effect of the probiotic Südamejuust (heart friendly cheese) comprising Lactobacillus plantarum TENSIA DSM 21380 on subjects with high-normal blood pressure: a randomized blinded controlled parallel three-arm study

Acronym
TE6

Study objectives
The consumption of probiotic cheese comprising the strain L. plantarum TENSIA helps to maintain normal blood pressure by reducing high-normal systolic and/or diastolic blood pressure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Review Committee on Human Research of the University of Tartu, 14/03/2011, ref: 205T-5

Study design
Randomized blinded controlled parallel three-arm study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Hypertension

Interventions
Participants randomised to active, placebo or control group will receive the intervention for 3 weeks:
1. Active intervention: probiotics cheese 50 g per day (probiotic Lactobacillus plantarum TENSIA dose: 10^10 colony forming units [CFU])
2. Placebo: 50 g control cheese
3. Control: no treatment

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Lactobacillus plantarum TENSIA probiotic cheese

Primary outcome measure

Decrease in systolic and/or diastolic blood pressure measured pre intervention, at the end of the intervention and also 1 week post intervention.

Secondary outcome measures
The following outcomes will be measured pre intervention, at the end of the intervention and also 1 week post intervention.
1. Body mass index (BMI)
2. Changes in inflammatory markers (WBC, hs-CRP)
3. Changes in lipidogram [total cholesterol and/or low density lipoprotein (LDL)-cholesterol and /or triglycerides]
4. Changes in fecal microflora
5. Persistence of ingested probiotic strain for 1 week
6. Blood, fecal and urine samples are collected at run-in, baseline and end of the study

Overall study start date
19/09/2011

Completion date
07/11/2011

Eligibility

Key inclusion criteria
1. Wish to participate
2. Aged 18 years and over
3. Baseline blood pressure levels high-normal according to European Society of Hypertension (ESH)/European Society of Cardiology (ESC) Guidelines for the Management of Arterial Hypertension (2007): systolic blood pressure (SBP) 130-139 mmHg, diastolic blood pressure (DBP) 85-89 mmHg, white blood cell (WBC) < 8.8x109 /L, high sensitivity C-reactive protein (hs-CRP) < 5 mg/L, glucose <6.0 mmol/L, serum creatinine F < 80 µmol/L, M: <106 µmol/L.
4. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120, 40 subjects in each arm

Key exclusion criteria
1. History of any gastrointestinal disease
2. Use of any antimicrobial drug within the last month

3. Use of any regular concomitant medication, including medical preparations including non-steroidal anti-inflammatory drugs and antioxidant vitamins
4. Food allergy
5. Diabetes and acute infection
6. Pregnancy or breastfeeding

Date of first enrolment
19/09/2011

Date of final enrolment
07/11/2011

Locations

Countries of recruitment
Estonia

Study participating centre
University of Tartu
Tartu
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Sponsor information

Organisation
BioCC OÜ

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Sponsor type
Industry

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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