ISRCTN29105501 https://doi.org/10.1186/ISRCTN29105501

Effect of the probiotic cheese on high-normal blood pressure

Submission date	Recruitment status	[ ] Prospectively registered
29/10/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/11/2012	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
Having high blood pressure (hypertension) increases the risk of serious problems such as heart attacks and strokes. Reducing blood pressure reduces the risk of heart disease and stroke. Lifestyle and diet changes are helpful for people whose blood pressure is higher than normal but not high enough to require drug treatment. The aim of this study is to assess the effect of a probiotic Edam-type cheese on blood pressure reduction.

Who can participate?
Generally healthy people aged 18 and over with elevated blood pressure, who do not take medication

What does the study involve?
Participants are randomly allocated to eat 50 g per day of either probiotic cheese or normal cheese. 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 effect of the probiotic.

What are the possible benefits and risks of participating?
Participants receive an assessment of their health status and if necessary, a free 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, as with any blood test there may be bruising and discomfort at the site of the blood test. The amounts of blood we are taking are small enough that they should not make you feel fatigue or cause anemia.

Where is the study run from?
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?
March to December 2012

Who is funding the study?
EU Structural Funds

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

Contact information

Type(s)
Scientific

Contact name
Dr Epp Songisepp

Contact details
Kreutzwaldi 1
Tartu
Estonia
51014
-
esongisepp@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
202M-25

Study information

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

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Review Committee, University of Tartu, 14/03/2011, ref: 202M-25

Study design
Randomized double-blind controlled parallel-designed two-armed intervention trial

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
Prehypertension

Interventions
Participants randomised to active or control group will be required during 4+4 weeks:
1. Active intervention: probiotics cheese 50g per day (probiotic Lactobacillus plantarum TENSIA daily dose: 10^10 colony forming units [CFU])
2. Control: 50 g control cheese without probiotic additive

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
(Systolic) blood pressure, measured pre intervention, after 4 weeks and at the end of the intervention

Secondary outcome measures
1. Reduction in DBP
2. Differences between verum and placebo in DBP values
3. Difference between verum and placebo in blood pressure values for the period 5 -8 weeks of product intake (by comparison of levels after 8 weeks with the levels after 4 weeks)
4. Samples are collected at run-in, baseline, after 4 weeks and at the end

Measured pre intervention, after 4 weeks and at the end of the intervention

Overall study start date
01/03/2012

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Wish to participate
2. Male and female subjects aged between 18 - 65 years with a body weight between 50 and 100 kg and a body mass index between 1829.9 kg/m2
3. High normal (130 - 139 / 85 - 89 mmHg) or hypertension grade 1 (140 - 159/90 - 99 mmHg) baseline blood pressure (BP) levels, as defined by ESH/ESC guidelines
4. Normal or not clinically significant deviations in safety laboratory values (clinical chemistry, blood count), WBC <8.8x 109/L, hs-CRP <5 mg/L; fasting glucose <6.0mmol/L, serum creatinine females <80 µmol/L, serum creatinine males <106 µmol/L, HbA1c < 6.5%
5. No use of any concomitant treatment which could influence the evaluation of the efficacy and tolerability of the investigational study product within one month prior to study start, including:
5.1. Supplementation with e.g. omega-3 fatty acids, omega-6 fatty acids, potassium, garlic, gingko biloba, polyphenols (e.g. quercetin), calcium, niacin, soy protein, green tea extract, oat fibre, plant sterols, psyllium seed husk or probiotics/probiotics
5.2. Intake of high amounts of walnuts
6. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150 (75 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 including non-steroidal anti-inflammatory drugs and antioxidant vitamins
4. Food allergy
5. Diabetes and acute infection
6. Pregnancy or breastfeeding
7. SBP ≤ 129 mmHg and/or DBP ≤ 84 mmHg
7.1. Hypertension grade > 1 as defined by a SBP ≥160 mmHg and/or DBP ≥100 mmHg
7.2. History (e.g. stroke) or clinical signs of cardiovascular abnormalities, in particular cardiac arrhythmia and bradycardia (pulse rate <50 beats per minute)

Date of first enrolment
01/03/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Estonia

Study participating centre
Kreutzwaldi 1
Tartu
Estonia
51014

Sponsor information

Organisation
BioCC OÜ

Sponsor details
Kreutzwaldi 1
Tartu
Estonia
51014
-
merlera@ut.ee

Sponsor type
Research organisation

Website
https://www.tptak.ee

Funder(s)

Funder type
Government

Funder Name

European Union (EU) Structural Funds, ref: EU30002

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