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Effect of a dietary supplement on high-normal blood pressure

Submission date
23/01/2015

Recruitment status
No longer recruiting

Registration date
06/02/2015

Overall study status
Completed

Last Edited
07/02/2022

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Increased blood pressure (hypertension) is widely accepted as a major cardiovascular risk factor. The reduction in blood pressure reduces the prevalence of cardiovascular diseases and stroke. Even a 2 mmHg lower usual SBP would lead to about 10% lower stroke mortality and about 7% lower mortality from ischaemic heart disease or other vascular causes in middle age and the reduction of SBP for 10 mmHg lower usual or 5 mmHg lower usual DBP would, in the long term, be associated with about 40% lower risk of stroke death and about 30% lower risk of death from vascular causes. The aim of this study is to assess a probiotic dietary supplement on blood pressure reduction.

Who can participate?
Generally healthy people, age 18–65 years, with an increase in blood pressure, who do not take medications.

What does the study involve?
The study population will be recruited from an already existing population (encoded) from the database. Additionally, participants will be recruited through media and social networks (e.g., Facebook), and e-mail lists of various professional associations. Participants will be randomly assigned to one of two arms for 8 weeks, followed by 2 weeks of washout: Lactobacillus plantarum TENSIA (150 mg per capsule) or control (placebo product in capsulated form containing microcellulose).

What are the possible benefits and risks of participating?
The study causes minimal inconveniences 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 anaemia. Study participants receive assessment of their health status and, if necessary, free consultation of a nutritionist and/or a specialist.

Where is the study run from?
Centre for Clinical and Physiological Research of the Bio-Competence Centre of Healthy Dairy Products LLC (Estonia)

When is the study starting and how long is it expected to run for?
April 2014 to June 2022

Who is funding the study?
BioCC OÜ (Estonia)

Who is the main contact?
Ms Merle Rätsep
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
235/T-11

Study information

Scientific Title
Effect of a dietary supplement containing Lactobacillus plantarum TENSIA on the subpopulation with high-normal blood pressure: a randomised controlled double-blind phase 2 study

Acronym
TEN

Study objectives
The consumption of a dietary supplement containing Lactobacillus plantarum TENSIA helps to maintain the normal blood pressure by reducing high-normal (systolic) blood pressure

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Review Committee on Human Research of the University of Tartu, 17/03/2014, reference number 235/T-11

Study design
Randomised controlled double-blind phase 2 study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
High-normal (130–139/85–89 mmHg) baseline blood pressure

Interventions
1. Healthy volunteers will be randomly allocated according to a random number table to one of two study arms and will take one capsule per day for 8 weeks followed by 2 weeks of washout:
1.1. Lactobacillus plantarum TENSIA 150 mg/day (hydroxypropyl methylcellulose): 7000 million colony-forming units
1.2. Control: placebo product in capsulated form containing microcellulose
2. Blood pressure, waist circumference, and bodyweight will be measured
3. Participants will be asked to assess their wellbeing and gastrointestinal effects, and provide blood, urine and fecal samples at every visit

Intervention Type
Supplement

Primary outcome(s)
Change in systolic blood pressure (SBP) at 8 weeks from baseline:
1. Measurements will be done with a mercury sphygmomanometer (Riester No 1002 DIPLOMAT presameter, Rudolf Riester GmbH, Germany)
2. Subjects will be instructed to avoid any strenuous exercise and stimulants (alcohol, caffeine) for at least 24 hours before any BP measurement and refrain from cold exposure, food and fluid intake and smoking for at least 1 hour before any BP measurement
3. All measurements will be done at the same time of day per subject and within 07:00 hours and 13:00 hours for all subjects by a properly trained practicing nurse at the Tartu University Clinics

Key secondary outcome(s))
1. Change in SBP at 4 weeks from baseline
2. Change in diastolic blood pressure (DBP) at 8 weeks from baseline
3. Change in DBP at 4 weeks from baseline
4. Change in SBP at 8 weeks from level at 4 weeks
5. Change in DBP at 8 weeks from level at 4 weeks

Measurements will be done with a mercury sphygmomanometer (Riester No 1002 DIPLOMAT presameter, Rudolf Riester GmbH, Germany); subjects will be instructed to avoid any strenuous exercise and stimulants (alcohol, caffeine) for at least 24 hours before any BP measurement and refrain from cold exposure, food and fluid intake and smoking for at least 1 hour before any BP

measurement; and all measurements will be done at the same time of day per subject and within 07:00 hours and 13:00 hours for all subjects by a properly trained practicing nurse at the Tartu University Clinics

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Desire to participate
2. Age 18–65 years
3. High-normal (130–139/85–89 mmHg) screening blood pressure
4. Normal or not clinically significant deviations in safety laboratory values (clinical chemistry, blood count), white blood cell count <8800 million/L, high-sensitivity C-reactive protein <5 mg/L; fasting glucose <6.0mmol/L, serum creatinine in females <80 µmol/L, serum creatinine in males <106 µmol/L, glycated haemoglobin < 5.9%
5. No use of any concomitant treatment including blood pressure lowering drugs (e.g., angiotensin-converting-enzyme inhibitors, blockers of beta adrenergic receptors, calcium channel blockers and diuretics) and lipid-lowering drugs (e.g., statins, bile acid sequestrates, cholesterol absorption inhibitors, nicotinic acid) that could affect the evaluation of the efficacy and tolerability of the investigational study product within 1 month before the study start.
6. Signed informed consent
7. Willingness to maintain a stable diet and physical activity level

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
23

Key exclusion criteria
1. History of any gastrointestinal disease
2. Use of any antimicrobial drug within past month
3. Use of any regular concomitant medication, including medical preparations, 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 (≥140–159 / 90–99 mmHg)
7.2. History or clinical signs of cardiovascular abnormalities (e.g., stroke), particularly cardiac arrhythmia and bradycardia (pulse rate <50 beats per minute)

Date of first enrolment
01/09/2014

Date of final enrolment
01/12/2020

Locations

Countries of recruitment
Estonia

Study participating centre
BioCC
Riia 181A
Tartu
Estonia
51014

Sponsor information

Organisation
BioCC OÜ

Funder(s)

Funder type
Not defined

Funder Name
Bio-Competence Centre of Healthy Dairy Products LLC Project EU 30002

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at registration.

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes