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Effect of the probiotic strain TENSIA® DSM21380 on high-normal blood pressure and up to grade-1 hypertension

Submission date	Recruitment status	[_] Prospectively registered
26/02/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/06/2018	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/06/2018	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 dietary supplement on blood pressure.

Who can participate?
Generally healthy people aged over 30 years with elevated blood pressure, who do not take blood pressure lowering medication

What does the study involve?
Participants are randomly allocated to take either a probiotic or a placebo (dummy) capsule once a day for 8 weeks. Participants are asked to assess their well-being and gastrointestinal (digestive) effects, and also to provide blood, urine and faecal samples to test the effect of the probiotic and treatment compliance.

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 clinician. 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. Collected blood amounts are small enough not to cause fatigue.

Where is the study run from?
BioCC LLC (Estonia)

When is the study starting and how long is it expected to run for?
Investigator initiated and funded

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Merle Rätsep
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Contact information

Type(s)
Scientific

Contact name
Miss Merle Rätsep

Contact details
Riia 181A
Tartu
Estonia
51014

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TC17-20

Study information

Scientific Title
Effect of a dietary supplement containing L. plantarum TENSIA® DSM21380 on subjects with high-normal blood pressure up to grade-1 hypertension: a randomised blinded placebo-controlled parallel designed two-armed study

Acronym
TC

Study objectives
The consumption of a dietary supplement containing L. plantarum TENSIA® DSM21380 has a beneficial effect on the blood pressure of subjects with high-normal blood pressure up to grade-1 hypertension.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the University of Tartu, 20/09/2017, ref: 272/T-15

Study design
Interventional multicentre randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Prehypertension

Interventions
Participants are randomly allocated to either the intervention group or the placebo group applying a 1:1 allocation ratio:
Group 1 (verum): Participants take one capsule daily for eight weeks. The capsule contains a daily dose of product containing 2x10e10 cfu of L. plantarum TENSIA®.
Group 2 (placebo): Participants take one capsule daily for eight weeks. The capsule contains a daily dose of product containing no active compounds (microcellulose).
Participants take the product daily for eight weeks and the last study visit will be performed two weeks after the end of the treatment.

Intervention Type
Supplement

Primary outcome measure
Change in systolic blood pressure (SBP) measured with a mercury sphygmomanometer at 8 weeks from baseline

Secondary outcome measures
1. Changes in SBP measured with a mercury sphygmomanometer at 4 weeks from baseline level and at 8 weeks from level at 4 weeks
2. Changes in diastolic blood pressure measured with a mercury sphygmomanometer at 8 weeks from baseline level, at 4 weeks from baseline level and at 8 weeks from level at 4 weeks
Changes at 8 weeks from baseline and at 4 weeks from baseline in the following outcome measures:
3. Oxidative stress indices and renin-angiotensin-aldosterone system (RAAS) indices measured from blood and urine samples using different ELISA based assays

4. Short chain fatty acids (SCFA) measured from stool samples using High Pressure Liquid Chromatography (HPLC)
5. Gut microflora indices (lactoflora, anaerobes etc) measured from stool samples using molecular approaches and specific primers

Overall study start date
03/10/2017

Completion date
30/12/2020

Eligibility

Key inclusion criteria
1. Written informed consent
2. Age over 30 years
3. Willingness to maintain a stable diet and physical activity level
4. Normal or not clinically relevant deviations in safety laboratory values
5. High normal or grade 1 systolic/diastolic blood pressure (≤159/99 mm Hg) with up to medium added risks in coronary-heart diseases
6. No use of any concomitant treatment (including blood pressure lowering drugs e.g. ACE-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)

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
200 (100 subjects in both groups)

Key exclusion criteria
1. Pregnancy and breastfeeding
2. (Food) allergy
3. Intolerance to the investigational product / its ingredients
4. Diabetes
5. Eating disorder
6. Active weight loss > 5 kg in prior 3 months
7. Extensive exercise (daily trainings of professional athletes)
8. Drug or alcohol abuse
9. Participation in other studies within the last 30 days / during the study
10. Any history of gastrointestinal diseases
11. Acute infection within the last 2 weeks prior to baseline
12. Use of any antimicrobial agents within the preceding 1 month

13. Donor within the last 1,5 months prior to start of the study (i.e. baseline visit)
14. Use of any pre-, probiotic or food supplement within the last 2 weeks prior to start of the study
15. Chronic inflammatory diseases

Date of first enrolment
03/10/2017

Date of final enrolment
01/10/2020

Locations

Countries of recruitment
Estonia

Study participating centre
BioCC LLC
Riia 181A
Tartu
Estonia
51014

Sponsor information

Organisation
BioCC LLC

Sponsor details
Kreutzwaldi 1
Tartu
Estonia
51014

Sponsor type
Research organisation

Website
www.biocc.eu

ROR
https://ror.org/02e801388

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/12/2021

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date