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Effect of a dietary supplement on blood pressure and oral microbiome

Submission date 13/05/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/05/2026	**Overall study status** Completed	
Last Edited 18/05/2026	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Public

Contact name
Dr Tiiu Kullisaar

Contact details
Ravila 19
Tartu
Estonia
50411
+372 (0)53485070
tiiu.kullisaar@ut.ee

Type(s)
Scientific

Contact name
Prof Reet Mändar

Contact details
Ravila 19
Tartu
Estonia
50411
+372 (0)5044291
reet.mandar@ut.ee

Additional identifiers

Study information

Scientific Title
Effect of a nitrate- and flavonoid-rich supplement on blood pressure and oral microbiome in resistant hypertension

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/06/2023, University of Tartu Ethics Review Committee on Human Research (Ülikooli 18a, Tartu, 50090, Estonia; +372 (0)7376215; kaire.kallak@ut.ee), ref: 379/T-6

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Essential hypertension stage I

Interventions
Patient randomization was performed by the partner institution (Ecosh Life OÜ) using a pre-established randomization scheme. The partner institution assigned each study participant a unique randomized subject number and the corresponding numbered dietary supplement kit. The randomized subject numbers and the matching kits were provided to the study nurse, who dispensed the study products to participants according to the assigned numbers.

The patients were randomly divided into two groups, the intervention group and the placebo group. The intervention group received dietary supplement capsules, the placebo group received rice powder capsules. Both capsules were prepared by Ecosh Life OÜ, the capsules and packages were without visible identifiers. The daily dose of dietary supplement capsules contained the following components: hesperidin 500 mg, extract of green tea (Camellia sinensis L.) 450 mg (containing epigallocatechin-3-gallate 203 mg), citrulline malate 400 mg, extract of green coffee beans 300 mg, beetroot powder 250 mg, extract of hawthorn berry (Crataegus laevigata) 180 mg, extract of grape seed (Vitis vinifera L.) 150 mg, folic acid (vitamin B9) 800 µg.

Both types of capsules were consumed once a day for 2 months. All patients continued consuming their prescribed medications during the trial period.

Intervention Type
Supplement

Primary outcome(s)
1. Brachial blood pressure (BP) measured using a validated oscillometric technique (OMRON M4-I; Omron Healthcare Europe BV, Hoofddorp, the Netherlands) in a sitting position from the nondominant arm as a mean of three consecutive measurements at 5-minute intervals, at baseline and 2 months

2. Arterial stiffness measured using sphygmocor apparatus (SphygmoCor, version 7.1; AtCor Medical, Sydney, NSW, Australia) at baseline and 2 months

3. Peripheral pressure waveforms from the radial/femoral arteries measured using a high-fidelity micromanometer (SPT-301B; Millar Instruments, Houston, TX, USA) at baseline and 2 months

4. Cortisol in saliva measured using standard method (ECLIA) at baseline and 2 months

5. 8-isoprostanes in urine measured using enzyme-linked immunosorbent assay (Cayman Chemical) at baseline and 2 months

6. Composition of salivary microbiome measured using Illumina NextSeq2000 system at baseline and 2 months

Key secondary outcome(s))

Completion date
24/11/2024

Eligibility

Key inclusion criteria
1. Essential hypertension stage I
2. A desire to participate
3. Age at least 18 years

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Heart failure (New York Heart Association [NYHA] 3-4)
2. Diabetes

Date of first enrolment
03/09/2023

Date of final enrolment
08/09/2024

Locations

Countries of recruitment
Estonia

Sponsor information

Organisation
University of Tartu

ROR
https://ror.org/03z77qz90

Funder(s)

Funder type

Funder Name
Ecosh Life OÜ

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available