Butyrate: Effect of Oral Administration in patients with Mild Hypertension

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22936

Source
Nationaal Trial Register

Brief title
BEAM

Health condition

hypertension

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Amsterdam UMC

Intervention

Outcome measures

Primary outcome

The primary outcome is average daytime systolic blood pressure as measured by 24-hour ambulatory blood pressure measurement

Secondary outcome

effect of oral butyrate:
- Average diastolic daytime ambulatory blood pressure, average systolic and diastolic night-time blood pressure and average systolic and diastolic 24-hour ambulatory blood pressure; Office blood pressure (two-weekly); Home blood pressure measurement (weekly)
- Faecal and plasma SCFA levels, including butyrate;
- Gut microbiome composition;
- Parameters of renal fluid and electrolyte balance regulation, including: weight and total body fluid as measured with body composition (using bio impedance analysis, BIA), plasma renin activity and aldosterone levels and sodium excretion in 24 hour urine;
- Change in immunophenotype, including levels of T-regulatory- and T-helper cells;
- Baroreceptor activity and pulse wave velocity as measured with Nexfin;
- Dietary intake (mijn.voedingscentrum.nl/nl/eetmeter).

Study description

Background summary

Intestinal SCFA (short chain fatty acids) are thought to be involved in blood pressure regulation via butyrate producing gutmicrobiota. In order to study the direct effects of SCFA butyrate, we will perform a double-blind randomized placebo-controlled trial in 50 patients with hypertension. Subjects will be treated with either 2 gram of sodium butyrate twice daily or placebo with equal amount of sodium chloride for 4 weeks. At baseline and after 4 weeks we will assess the primary endpoint which is effect of oral butyrate on 24h blood pressure; secondary objectives are to assess the effect of oral butyrate on plasma and faecal SCFA levels, gut microbiome composition, natriuresis and diuresis, renin and aldosterone levels, immunophenotype, hemodynamic parameters such as baroreceptor sensitivity and pulse wave velocity, and changes in weight and body composition.

Study objective

SCFA butyrate supplementation affects blood pressure

Study design

Baseline, 2 (only office blood pressure and BIA) and 4 weeks (active treatment) as well as 5 weeks (washout)

Intervention

either 2 gram of sodium butyrate twice daily or placebo with equal amount of sodium chloride for 4 weeks.

Contacts

Public
AMC
max nieuwdorp

0031 20 5666612
Scientific
AMC
max nieuwdorp

0031 20 5666612

Eligibility criteria

Inclusion criteria

Age between 40 and 65 years
- For females: postmenopausal status
- Caucasian
- Mild hypertension (defined as systolic blood pressure between 140 and 159 mmHg and/or diastolic blood pressure between 90 and 99 mmHg) OR use of 1 antihypertensive drug due to hypertension and willing to temporarily stop this medication during the study
- BMI lower than 27 kg/m2

Exclusion criteria

- Use of betablockers
- Known secondary causes of hypertension such as renal artery stenosis, adrenal or thyroid disease
- History of cardiovascular disease: angina pectoris, myocardial infarction, cerebrovascular accident, transient ischemic attack, peripheral artery disease, heart failure.
- History of diabetes mellitus
- Current smoking
- Antibiotics usage within three months before inclusion
- Having a severe disease of the digestive tract, such as celiac disease, Crohn’s disease, active
ulcerative colitis or short bowel syndrome.
- Impaired renal function, defined as an estimated glomerular filtration rate (eGFR) lower than 60

ml/min/1,73m2 using the CKD-EPI formula

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
n/a

Ethics review

Positive opinion

Date:	24-09-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8924
Other	METC AMC : 2020_106

Study results

Summary results
follow