Long-term effects of a potato-based food pattern vs a rice / pasta-based food pattern on fasting & postprandial cardiometabolic health; The LoPoCardio - trial

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The objective is to evaluate the effects of longer-term consumption of diets rich in boiled potatoes versus those rich in rice or pasta on established cardiovascular risk parameters.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON56420

Source
ToetsingOnline

Brief title
Potatoes and cardiometabolic health

Condition

- Metabolism disorders NEC

Synonym
diabetes, glucose metabolism

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Alliance for Potato Research & Education (APRE)

Intervention

Keyword: Cardiometabolic health, Metabolism, Nutrition, Potatoes

Outcome measures

Primary outcome

In order to examine the impact of potato versus pasta / rice consumption on chronic glucose metabolism the primary outcome parameter of this study is a change in average daily glucose concentration measured over a 15 hours period between waking up and going to bed 7:00AM - 22:00PM for three consecutive days.

Secondary outcome

To investigate if potato consumption changes glucose metabolism, lipid metabolism and low-grade inflammation, general wellbeing, and vascular function.

Study description

Background summary

Current international dietary guidelines emphasize that the majority of our energy intake should be carbohydrate-derived. These carbohydrates should have a low glycemic index (low-GI). In addition, *low-carb* diets have received a lot of attention lately, assuming that high intakes of carbohydrates result in unhealthy metabolic profiles and concomitant disease developments. Given the observations in the so-called blue zones, - areas of exceptional longevity around the world -, it is questionable whether high intakes of carbohydrate-rich staple foods (often with a high-GI) are indeed unhealthy. To breach the current controversies and answer the question whether potatoes do align with the current dietary guidelines, there is an urgent need for

well-designed controlled human intervention trials evaluating the true impact of potato consumption as part of a healthy dietary pattern on cardiometabolic health.

Study objective

The objective is to evaluate the effects of longer-term consumption of diets rich in boiled potatoes versus those rich in rice or pasta on established cardiovascular risk parameters.

Study design

A longer-term randomized well-controlled intervention trial with a parallel design.

Intervention

During the intervention period, 28 subjects will consume a potato-based dietary pattern providing about 300 gr boiled potatoes daily. This will be compared with a group of 28 subjects consuming a white rice / white pasta-based dietary pattern containing an iso-energetic amount of white rice / white pasta.

Study burden and risks

Venipuncture can occasionally cause a local hematoma or bruise to occur. Some study subjects may report pain during venipuncture. Insertion of the cannula can cause some discomfort and possible a hematoma or bruise. Some study subjects may also report pain during the insertion of the cannula. In total 308.5 mL blood will be sampled spread over a timeframe of 12 weeks and 7 blood sampling moments with at least three weeks between subsequent blood sampling moments. All measurements are routine and are not expected to lead to physical side effects.
During the postprandial tests, subjects have to stay at the university and may not eat. The investigational products, i.e. the potatoes, pasta and rice provided, are safe and also commercially available. In addition, all ingredients to prepare the mixed meals for the postprandial test day are commercially available in the supermarket and approved for human consumption. There are no side effects for the milkshakes when used in our earlier experiments.
Time investment for the participants is approximately 16.2 hours, excluding travel time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Men and women
- Aged between 40-70 years
- BMI between 25-35 kg/m2 (overweight and obese)
- Serum total cholesterol < 8.0 mmol/L (further testing is recommended for excessive hyperlipidemia [serum total cholesterol >= 8.0 mmol/L] according to the Standard for cardiovascular risk management of the Dutch general practitioners community [NHG])
- Serum triacylglycerol < 4.52 mmol/L
- No current smoker
- No diabetic patients
- No familial hypercholesterolemia
- No abuse of drugs

- Not more than 4 alcoholic consumption per day with a maximum of 21 per week
- Stable body weight (weight gain or loss < 3 kg in the past three months)
- No use of medication known to treat blood pressure, lipid or glucose metabolism
- No use of an investigational product within another biomedical intervention trial within the previous 1-month
- No severe medical conditions that might interfere with the study, such as epilepsy, asthma, kidney failure or renal insufficiency, chronic obstructive pulmonary disease, inflammatory bowel diseases, auto inflammatory diseases and rheumatoid arthritis
- No active cardiovascular disease like congestive heart failure or cardiovascular event, such as an acute myocardial infarction or cerebrovascular accident
- Willingness to give up being a blood donor from 8 weeks before the start of the study, during the study and for 4 weeks after completion of the study
- No difficult venipuncture as evidenced during the screening visit
- Willing to comply to study protocol during study
- Informed consent signed

Exclusion criteria

- Allergy or intolerance to potatoes, pasta or rice
- Serum total cholesterol >= 8.0 mmol/L
- Serum triacylglycerol >= 4.52 mmol/L
- Current smoker, or smoking cessation <12 months
- Diabetic patients
- Familial hypercholesterolemia
- Abuse of drugs
- More than 4 alcoholic consumptions per day or 21 per week
- Unstable body weight (weight gain or loss > 3 kg in the past three months)
- Use medication known to treat blood pressure, lipid or glucose metabolism
- Use of an investigational product within another biomedical intervention trial within the previous 1-month
- Severe medical conditions that might interfere with the study, such as epilepsy, asthma, kidney failure or renal insufficiency, chronic obstructive pulmonary disease, inflammatory bowel diseases, auto inflammatory diseases and rheumatoid arthritis
- Active cardiovascular disease like congestive heart failure or cardiovascular event, such as an acute myocardial infarction or cerebrovascular accident
- Not willing to give up being a blood donor from 8 weeks before the start of the study, during the study or for 4 weeks after completion of the study
- Not or difficult to venipuncture as evidenced during the screening visit
- Use of over-the-counter and prescribed medication or supplements, which may interfere with study measurements to be judged by the principal investigator;

- Use of oral antibiotics in 40 days or less prior to the start of the study;
- Blood donation in the past 3 months before the start of the study
- Not willing to comply to study protocol during study or sign informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-03-2021
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	24-12-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-04-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT04851041
CCMO	NL71526.068.19