Long-term effects of mixed nuts consumption on brain vascular function in elderly men and women.

Published: 11-12-2019
Last updated: 10-04-2024

The primary objective is to evaluate in elderly men and women the effect of 16-week mixed nut consumption on cerebral blood flow, as quantified by the non-invasive gold standard magnetic resonance imaging (MRI)-perfusion method Arterial Spin...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON48256

Source
ToetsingOnline

Brief title
Mixed nuts and brain vascular function.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Insulin Resistance Syndrome, Metabolic Syndrome, Syndrome X

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: The International Nut and Dried Fruit Council (INC).

Intervention

Keyword: Mixed nuts, Vascular function

Outcome measures

Primary outcome

At baseline, first anthropometric measurements will be performed and blood pressure will be determined. In addition, a fasting blood sample will be drawn. Another fasting blood sample will be draw at eight weeks, while participants have to attend the research facilities two times to perform follow-up measurements after sixteen weeks. The primary endpoint is the difference at follow-up in cerebral blood flow, as assessed by ASL, between interventions.

Secondary outcome

Secondary endpoints are the cerebral blood flow response to intranasal insulin delivery as quantified by ASL, and cognitive functioning as assessed with a neuropsychological test battery.

Study description

Background summary

Impaired brain vascular function precedes the development of reduced cognitive performance, while brain insulin-resistance is also associated with cognitive decline. The Mediterranean diet, which is rich in nuts, may protect against the development of impaired cognitive performance. We hypothesize that long-term mixed nut consumption increases brain insulin-sensitivity thereby improving brain vascular function and cognitive performance.

Study objective

The primary objective is to evaluate in elderly men and women the effect of 16-week mixed nut consumption on cerebral blood flow, as quantified by the non-invasive gold standard magnetic resonance imaging (MRI)-perfusion method

Arterial Spin Labelling (ASL). Cerebral blood flow is a robust and sensitive physiological marker of brain vascular function. Secondary objectives are to investigate effects on the cerebral blood flow response to intranasal insulin delivery - a marker of insulin-sensitivity in the human brain - as quantified by ASL, and cognitive functioning as assessed with a neuropsychological test battery.

Study design

This intervention study will have a randomized, controlled, cross-over design. The total study duration will be 40 weeks, including two 16-week interventions, separated by a washout period of at least 8 weeks.

Intervention

Subjects will receive in random order daily 60 g of mixed nuts (15 g of walnuts, 15 g of cashews, 15 g of hazelnuts, and 15 g of pistachios) (nut intervention) or no nuts for 16 weeks (control intervention), separated by a wash-out period of at least 8 weeks.

Study burden and risks

Subjects will be screened to determine eligibility during one visit of 20 minutes. During these screening visits, anthropometric measurements will be performed and blood pressure will be determined. In addition, a fasting blood sample (5.5 mL) will be drawn. During nut intervention, adults will receive daily 60 g of mixed nuts for sixteen weeks. These regimens were well-tolerated in previous trials and are safe, and there are no expected side effects related to the nut consumption. During the trial on different occasions, tests will be performed and blood will be sampled (a total of 325.5 mL during the whole trial). During these tests, subjects have to stay at the university and are not allowed to eat. Some subjects may report pain during venipuncture. Insertion of the cannula can cause some discomfort and possible a hematoma or bruise. Some adults may also report pain during the insertion of the cannula. ASL perfusion MRI non-invasively records cerebral blood flow without any significant risks. Measurements will be performed on a Siemens 3.0 Tesla Magnetom Prisma Fit scanner. No contrast medication or radioactive tracer substance will be administered. Brain insulin-sensitivity will be assessed by quantifying acute effects of insulin as nasal spray on cerebral blood flow, which is safe and follows what is being used by experts at the University of Tübingen (Germany) and Leiden University Medical Centre (protocol code numbers P13.164 and NL45043.058.13), who we are closely collaborating with. Other measurements are routine and are also not expected to lead to physical side effects. Participants that not fully adhere to the study protocol will be excluded from the statistical analyses, because a per protocol analysis will be performed. The total time investment is 19 hours (1140 minutes), excluding travel time.

The study will provide insight into the potential beneficial effect of mixed nuts on brain vascular function in elderly adults.

Contacts

Public
Universiteit Maastricht

Universiteitsingel 50
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitsingel 50
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Aged between 60-70 years
- BMI between 25-35 kg/m2
- Fasting plasma glucose < 7.0 mmol/L
- Fasting serum total cholesterol < 8.0 mmol/L
- Fasting serum triacylglycerol < 4.5 mmol/L
- Systolic blood pressure < 160 mmHg and diastolic blood pressure < 100 mmHg
- Stable body weight (weight gain or loss < 3 kg in the past three months)
- 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

Exclusion criteria

- Allergy or intolerance to nuts
- Left handedness
- Current smoker, or smoking cessation < 12 months
- Diabetic patients
- Familial hypercholesterolemia
- Abuse of drugs
- More than 3 alcoholic consumptions per day
- Use of nuts or dietary supplements known to interfere with the main outcomes as judged by the principal investigators
- Use medication 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
- Contra-indications for MRI imaging (e.g. pacemaker, surgical clips/material in body, metal splinter in eye, claustrophobia)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	23-01-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	11-12-2019
Application type:	First submission
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
CCMO	NL71168.068.19