Aronia and Cognitive Fitness: Focus on Brain Insulin-Sensitivity and Vascular Function

Published: 08-03-2022
Last updated: 05-04-2024

The primary objectives are to investigate effects of AME intake on brain vascular function and insulin-sensitivity in cognitive-control brain areas, while we will also evaluate changes in cognitive function (secondary objective).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55924

Source
ToetsingOnline

Brief title
Aronia and cognitive fitness

Condition

- Other condition

Synonym
cognition

Health condition

cognitief functioneren

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: BioActor BV,Stichting Life Sciences Health - TKI (trade name Health Holland)

Intervention

Keyword: aronia, brain, cognition, vascular function

Outcome measures

Primary outcome

Cerebral blood flow responses before and after intranasal insulin

administration will be non-invasively quantified by MRI.

Secondary outcome

Furthermore, effects of AME on cognitive performance will be assessed.

Exploratory outcomes are other potential mechanisms responsible for observed

effects on cognitive function, and other perceivable benefits such as vascular

improvements and metabolic markers.

Study description

Background summary

Previously, we have observed beneficial effects of Aronia Melanocarpa extract (AME) supplementation on cognitive performance in healthy middle-aged adults. However, underlying mechanisms have not yet been addressed. In addition, effects of AME are unknown in subjects at increased risk of cognitive impairment. We hypothesize that supplementation with AME enhances (regional) brain vascular function and brain insulin-sensitivity, thereby improving cognitive function of subjects at increased risk of cognitive impairment.

Study objective

The primary objectives are to investigate effects of AME intake on brain vascular function and insulin-sensitivity in cognitive-control brain areas,

while we will also evaluate changes in cognitive function (secondary objective).

Study design

The present study is a randomized, double-blind, placebo-controlled, cross-over trial consisting of two study groups and a pre- and post-test day in both study arms.

Intervention

Participants will receive, in random order, daily 160 mg of an anthocyanin-rich Aronia extract (containing 40 mg anthocyanins) or a placebo for six weeks, separated by a 12-week wash-out.

Study burden and risks

The total study duration will be 24 weeks, including the wash-out period of 12 weeks. During the study, blood samples will be collected (< 500 mL in total), which may cause a hematoma or bruise. Furthermore, ASL MRI is a non-invasive method, without significant risks. No contrast medication or radioactive tracer will be administered. The use of insulin as nasal spray is safe and already used in multiple studies from our department. Other measurements are not expected to cause side effects. Subjects will have a time investment of ±11.5 hours (screening, four test days, 24hr bp e.g.). A similar dose of AME has already been used in previous studies, with no side effects.

Contacts

Public
Universiteit Maastricht

Universiteitsingel 50
Maastricht 6229ER
NL
Scientific
Universiteit Maastricht

Universiteitsingel 50
Maastricht 6229ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

men and women, age 55-75, BMI 25-35 kg/m2

Exclusion criteria

smoking, diabetes mellitus, active cardiovascular disease, severe medical conditions, use of supplements or medication affecting main outcomes, contra-indications for MRI

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-06-2022
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	08-03-2022
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	NL80072.068.21