Evaluating kinetics and bioavailability of Aronia Melanocarpa extract in healthy young and older adults

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The main objective of this study is to study the bioavailability and pharmacokinetics of acute Aronia Melanocarpa supplementation in healthy young (18-35 years) and older adults (55-75 years) adults.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56259

Source
ToetsingOnline

Brief title
Bioavailability of Aronia Melanocarpa (BAM)

Condition

- Other condition

Synonym
absorption, bioavailability, pharmacokinetics

Health condition

farmacokinetiek

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: BioActor BV

Intervention

Keyword: aronia melanocarpa, bioavailability, pharmacokinetics

Outcome measures

Primary outcome

The bioavailability and pharmacokinetics of AME will be assessed via frequent blood sampling, urine collection, and faecal sampling, in which AME and metabolite profiles will be quantified. Blood samples will be collected at t=0h, t=0.5h, t=1h, t=1.5h t=2h, t=2.5h, t=3h, t=4h, t=6h, t=8h, t=10h, t=12h, t=24h, t=48h following AME intake. Urine samples will be collected at t=0h, and in 6 different time intervals, i.e. t=0-4h, t=4-8h, t=8-12h, t=12-16h, t=16-24h, and t=24h-48h. Available faecal samples will be collected and combined into one sample until t=48h on a voluntary basis.

Secondary outcome

n.a.

Study description

Background summary

Anthocyanins are a subgroup of flavonoids (polyphenolic compounds) that are mainly found in berries. Anthocyanins and their associated metabolites, such as cyanidin-3-glycosides, are generally recognized for their health benefits. For example, they cross the blood-brain barrier, where they can act as promising agents for the prevention of neurodegenerative diseases. Moreover, effects on vascular function and consequently cardiovascular risk reduction have also been described. A high concentration of anthocyanins is found in Aronia Melanocarpa

(AME). As the dietary intake of anthocyanins in the population is considered low, supplementation is considered an important approach to improve plasma levels. Since ageing changes physiological processes like gastrointestinal tract motility, liver and renal function, metabolism, absorption, and enzyme activity, anthocyanin metabolism and bioavailability might differ between younger and older age groups. Currently, bioavailability studies where metabolites in different age groups are compared side by side are lacking. This knowledge is relevant since the necessary dietary intake to reach a certain threshold concentration in the circulation could be different in younger and older subjects.

Study objective

The main objective of this study is to study the bioavailability and pharmacokinetics of acute Aronia Melanocarpa supplementation in healthy young (18-35 years) and older adults (55-75 years) adults.

Study design

The present study is a pharmacokinetic study, carried out in two age groups.

Intervention

During the test day, participants will ingest a drink consisting of 65 mg AME (16 mg anthocyanins), and 200 ml water.

Study burden and risks

The participants have to stay at the research facility for 12 hours. During the study, blood samples will be collected 14 times using a cannula, which may cause bruising or hematoma. Furthermore, participants will provide urine and faecal samples for 48 hours in total. From 72 hours before the visit, participants must adhere to specific dietary restrictions. The participants will not benefit directly from participation. The AME dose has already been used in previous studies, with no side effects.

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 18-35 years, or between 55-75 years old
• BMI between 18-35 kg/m2
• 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

Exclusion criteria

• Smoking or smoking cessation < 12 months
• Severe medical conditions, including asthma, kidney failure, auto-inflammatory diseases, rheumatoid arthritis, diabetes mellitus, cardiovascular disease, gastrointestinal disorders such as Crohn*s disease, colitis
• Use of dietary supplements or medication affecting the main outcomes of the study (e.g. affecting gut metabolism, blood pressure medication)
• Use of an investigational product within another biomedical intervention trial within the previous month
• Abuse of drugs
• More than 3 alcoholic consumptions per day

• Known pregnancy or lactation
• Known allergy to study product
• Difficult venepuncture

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-03-2024
Enrollment:	20
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	27-12-2023
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
ClinicalTrials.gov	NCT06306911
CCMO	NL85015.068.23