Two apples a day, keep the doctor away?

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Primary objectives:- Investigate whether the activity of the bacterial enzyme β-glucuronidase and the abundance of β-glucuronidase-producing bacteria could be decreased by ingestion of 2 apples a day for a period of 6 weeks -...

Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON53962

Source
ToetsingOnline

Brief title
Apple study

Condition

- Gastrointestinal conditions NEC
- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
GUS metabolisme in case of increased pectin intake

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: &beta, estrogen, -glucuronidase, microbiome, pectin

Outcome measures

Primary outcome

Primary endpoints:

- Significant decrease in the activity of the bacterial enzyme β-glucuronidase

and the abundance of β-glucuronidase-producing bacteria

- Assessment with WMGS of the gut microbiota composition, diversity, and

functional capacity

- The frequency of the eating of two apples a day

Secondary outcome

Secondary endpoints:

- Significant increase of SCFA

- Significant change in dietary intake, medication, stool classification and

frequency, blood pressure, weight and quality of life

Study description

Background summary

Rationale:
Studies have shown that higher blood levels of estrogen are related to an increased risk of developing breast cancer. While there are many different factors affecting these levels, the microbiome has been linked as a key factor. Not only the composition of the gut microbiota plays a role here, but also its activity is of special interest. The gut microbiota for instance produces the bacterial enzyme β-glucuronidase which has been shown to de-conjugate biliary excreted estrogens, leading to reactivation and reabsorption of estrogens into the bloodstream. It might be expected that this reabsorption results in elevated blood estrogen levels. These elevated levels of estrogen have been linked to not only development but also recurrence of breast cancer. Apples are known for their pectin which has prebiotic properties and a potential decreasing effect on β-glucuronidase activity. In vitro studies and animal studies have already shown the β-glucuronidase decreasing impact of pectin. In

humans this was never examined before.

That is why this study aims to investigate whether it is possible to lower the activity of the bacterial enzyme β-glucuronidase and the abundance of β-glucuronidase-producing bacteria by a simple dietary intervention. This dietary intervention consists of the ingestion of two whole apples a day, one in the morning and one in the evening, during the period of 6 weeks.

We hypothesize to see a decrease in the activity of the bacterial enzyme β-glucuronidase and the abundance of β-glucuronidase-producing bacteria.

Study objective

Primary objectives:
- Investigate whether the activity of the bacterial enzyme β-glucuronidase and the abundance of β-glucuronidase-producing bacteria could be decreased by ingestion of 2 apples a day for a period of 6 weeks
- Examine changes in gut microbiota composition, diversity, and functional capacity
- Examine feasibility of eating 2 apples a day for a period of 6 weeks

Secondary objectives:
- Investigate whether fecal levels of short-chain fatty acids (SCFA) increase during the intervention period
- Examine whether the impact of eating apples reaches further, we will investigate dietary intake, medication, stool classification and frequency, blood pressure, weight, length and quality of life before and after the intervention

Study design

in-participant comparison, intervention study

Intervention

the eating of two apples a day during a period of 6 weeks

Study burden and risks

There are limited risks associated with participation in this research. The risks for the participants are minimal and consists of the following:
- The ingestion of whole apples could harm the teeth
- Further participants, who have never been eating apples before, could experience an apple allergy

The burden for the patient is minimal and consists of the following:

- The eating of the apples and add a sticker to anapple journal
- Blood pressure, length and weight measurement at home/hospital
- 2 x 15 minutes to fill in the questionnaires (at the start and end) on quality of life and general wellbeing
- 2 x 15 minutes to fill in the food diary and stool scale
- 2x collection of fecal sample with a patient-friendly collection kit (already successfully applied in other studies)

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Age 50-64
Postmenopausal women
Recent negative breast cancer screening (< 6 months)

Exclusion criteria

Previous gastrointestinal surgery (excl. appendix surgery)
any type of cancer in history, except for basal cell carcinoma (BCC)
inflammatory bowel disease
mammography older than 6 months
antibiotic use within three months before fecal sampling
physically or mentally incapable or incompetent to sign informed consent
known apple allergy or complaints matching with apple allergy
less good dental state
the regularly consumption of 1 or more apples a day

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-07-2023
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	18-04-2023
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
CCMO	NL82475.068.22