Bioavailability of lutein from potatoes.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28982

Source
NTR

Brief title
Bioavailability lutein

Health condition

bioavailability lutein potatoes
biobeschikbaarheid luteine aardappelen

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG),
Antonius Deusinglaan 1,
9713 AV Groningen
Source(s) of monetary or material Support: Food & Nutrition Delta (Ministerie van Economische Zaken, Landbouw en Innovatie)

Intervention

Outcome measures

Primary outcome

To investigate the bioavailability and pharmacokinetics of 13C- lutein/zeaxanthin from lutein/zeaxanthin-enriched potatoes in healthy volunteers.

Secondary outcome

To monitor 13CO2 in breath and investigate 13C-metabolites in urine.

Study description

Background summary

Rationale:

Lutein and zeaxanthin are two carotenoids which are associated with lowering the risk of cardiovascular disease and age-related macular degeneration. However, consumption of green leafy vegetables which are an important source of lutein/zeaxanthin are decreasing. A potato strain which is especially rich in lutein/zeaxanthin could potentially contribute to the daily intake of lutein/zeaxanthin. However, bioavailability of lutein/zeaxanthin from these potatoes is not yet known.

Objective:

To investigate the bioavailability of lutein/zeaxanthin from lutein/zeaxanthin-rich potatoes in healthy volunteers.

Study design:

Volunteers will receive a single test meal and subsequently plasma will be collected for a time period of 10 days in decreasing frequency.
Study population: Healthy human volunteers between 18 and 30 yrs of age with a BMI between 18.5 and 24.9.

Intervention:

Six volunteers (3 men, 3 women) will ingest mashed potatoes made from lutein/zeaxanthin-rich potatoes which are labeled with the stable isotope 13C.

Main study parameters/endpoints:

The main study parameter is the plasma concentration of 13C- and 12C-lutein/zeaxanthin, which will be monitored during 10 days at time points: 0, 1, 2, 3, 4, 5, 6, 10, 12, 33, 48, 72, 96, 168 and 216 h after ingestion.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The volunteers need to stay one day in the UMCG (day one). A cannula will be inserted for blood collection and 10 blood samples will be collected. The next day the volunteers come back for two single blood collections. The volunteers need to come back for a single blood collection twice on day two and once for another six days. Per time point 5 ml blood will be collected, which amounts to 85 ml over the whole study period. In addition breath (day one) and urine samples (morning of day one and day two) will be collected. The test meals are food products which are not posing any risk to the health of the volunteers. The volunteers will fill in a questionnaire concerning habitual food intake and will register intake of lutein/zeaxanthin rich products during the study period.

Study objective

Lutein and zeaxanthin are two carotenoids which are associated with lowering the risk of cardiovascular disease and age-related macular degeneration. However, consumption of green leafy vegetables which are an important source of lutein/zeaxanthin are decreasing. A potato strain which is especially rich in lutein/zeaxanthin could potentially contribute to the daily intake of lutein/zeaxanthin. However, bioavailability of lutein/zeaxanthin from these potatoes is not yet known.

Study design

1. Breath samples:

One basal breath sample will be collected after placement of the venous cannula. The first 6 hours after ingestion of the test meal samples will be collected half-hourly, the last hours hourly;

2. Blood samples:
On day 1 one basal blood sample will be collected directly after placement of the venous cannula. Then blood samples are collected 1, 2, 3, 4, 5, 6, 8, 10 and 12 h after ingestion of the test meal.
On day 2 on blood sample will be collected in the morning and at the end of the afternoon.
On day 3, 4, 5, 8, 10 one blood sample will be collected in the morning;

3. Urine samples:

One morning urine sample will be collected by the volunteers at home at day 1 and day 2 of

the study.

Intervention

The volunteers will ingest 200 g of mashed lutein/zeaxanthin-rich potatoes of which 50 g is made from 13C-labeled lutein/zeaxanthin-rich potatoes.To the mashed potatoes 7 g olive oil will be added to facilitate absorption of lutein/zeaxanthin in the small intestine. The volunteer will drink 250 mL of water with the mashed potatoes.

Contacts

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Eligibility criteria

Inclusion criteria

1. 18 - 30 yr;

2. Used to eat breakfast (solid food);

3. BMI between 18.5 and 24.9;

4. Apparently healthy;

5. Signed written informed consent form (ICF).

Exclusion criteria

1. Diabetes mellitus;

2. Gastrointestinal disorders;

3. Undergone digestive tract surgery except appendectomy);

4. Vegetarian;

5. Donation of blood within the last 3 months prior to the start of the experiment;

6. Use of medication (inclusive oral contraceptive pill);

7. Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2012
Enrollment:	6
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-06-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37412
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3363
NTR-old	NTR3511
CCMO	NL39206.042.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37412

Study results

Summary results
N/A