Ontwikkeling van een methode voor het bestuderen van de omzetting van beta-caroteen in vitamine A.

No registrations found.

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

Summary

ID

NL-OMON25920

Source
NTR

Brief title
CARRET Pilot Study

Health condition

Vitamin A deficiency, bioequivalence

Sponsors and support

Primary sponsor: Wageningen University & Research
Source(s) of monetary or material Support: PepsiCo

Intervention

Outcome measures

Primary outcome

13C10 isotope enrichment in plasma retinol

Secondary outcome

Bioconversion of 13C10-betacarotene to 13C5-retinol

Study description

Background summary

Rationale: Vitamin A (retinol) deficiency is still a public health concern in developing countries. Stable isotope techniques are now used to accurately assess vitamin A status and to determine bioequivalence and bioconversion of β-carotene (provitamin A) to retinol.
Objective: To explore the potential of a novel retinol stable isotope dilution technique to assess the bioconversion and bioequivalence of dietary provitamin A.
Study design: This pilot study will be a 4-week double blind parallel interventional trial.
Study population: Female (n = 16) volunteers aged between 18-35 years will be recruited from the human volunteer database kept at Wageningen University and Research.
Intervention: Subjects will be randomly allocated to four treatment groups of equal size (n=4; group A–D). All subjects will be provided with a standardised meal on the evening before start of the study which they will consume at home between 18h00 and 20h00. They will additionally be asked to abstain from any food or beverage consumption, except water, until the next morning. At baseline (day 0) fasted blood samples will be collected from subjects, where after they will receive a once-off dose of 13C10-labelled β-carotene (2 mg) dissolved in high oleic sunflower oil as a capsule. Blood will subsequently be collected at 2, 4, 6, 8, 10, and 12 hours post dose via cannulation. Subjects will be provided with a standardized breakfast (after 2h blood draw), lunch (after 4h blood draw), and dinner (after 8h blood draw). The next day, after a fasting blood sample has been drawn (24h), subjects will receive a once-off dose of 13C10-labelled retinol (1 mg). For the duration of the rest of the study all subjects will daily receive a capsule containing 80 µg 13C10-labeled retinol (as retinyl acetate) and a capsule with a varying dose of unlabelled retinol (as retinyl acetate): group A, 150 µg; group B, 300 µg; group C, 500 µg; and group D, 800 µg. Additional fasting blood samples will be collected at day 7, day 14, day 21 and day 28 (end point). Subjects will be asked not to deviate from their habitual diets during the study, and intake of vitamin A rich products such as liver and supplements will be restricted.
Main study parameters/endpoints: Percentage of 13C10-labelled retinol in plasma with intakes of varying doses of unlabelled retinol over time (4 weeks), and the shape of the dose response curve. In addition, we will measure the area under the curve (AUC) of 13C10-labelled β-carotene and 13C5-labelled retinol in blood plasma over a 24h period.

Study objective

We hypothesize that with this new stable isotope dilution method we will be able to assess the bioequivalence of dietary pro-vitamin A intake in future studies.

Study design

Day 1: 0h, 2h, 4h, 6h, 8h, 12h and 24h

Thereafter: Days 7, 14, 21, 28

Intervention

Group A: 150 mcg retinol/day; Group B: 300 mcg retinol/day; Group C: 500 mcg retinol/day; Group D: 800 mcg retinol/day

Contacts

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Eligibility criteria

Inclusion criteria

• Female
• Age: 18-35 years
• Non-smoking
• BMI 18-25 kg/m2
• Fluent in Dutch

Exclusion criteria

 Pregnant or lactating
 Metabolic diseases (diabetes, hypercholesterolemia)
 Disorder or use of drugs that interferes with fat-soluble vitamin absorption
 History of chronic diseases including renal disease, liver disease, diagnosed gastrointestinal disorders and cancer
 Allergic to food that will be provided during the study
 Recent major surgery, blood transfusion or blood donation (< 6 months ago)
 Dieting or having irregular dietary habits

 Use of (multi)vitamin preparations with vitamin A or β-carotene up till 3 months before the start of the study
 Participation in another clinical trial
 Being an MSc student or employed at the Division of Human Nutrition and Health, Wageningen University

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-03-2020
Enrollment:	16
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
Not applicable

Ethics review

Positive opinion

Date:	07-02-2020
Application type:	First submission

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
NTR-new	NL8362
Other	METC-WU : Carret (20/03)

Study results

Summary results
One publication in an international peer reviewed journal (Open Access)