Bioavailability of lutein from a lutein-enriched egg-yolk-beverage and its dried re-suspended versions.

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The primary objective of this study is to investigate whether consumption of a dried lutein-enriched egg-yolk containing beverage significantly increases serum lutein concentration in healthy volunteers.A secondary objective is to investigate...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anterior eye structural change, deposit and degeneration
Study type	Interventional

Summary

ID

NL-OMON35978

Source
ToetsingOnline

Brief title
Lutein bioavailability from fresh and dried beverages

Condition

- Anterior eye structural change, deposit and degeneration
- Vitamin related disorders

Synonym
age-related macular degeneration (AMD)

Research involving
Human

Sponsors and support

Primary sponsor: Newtricious b.v.
Source(s) of monetary or material Support: Innovatieprogramma Food & Nutrition;Food

& Nutrition Delta (FND);FND10004

Intervention

Keyword: beverage, bioavailability, egg yolk, lutein

Outcome measures

Primary outcome

Lutein serum concentrations will be measured before and after the three weeks run-in period and after finishing the whole treatment. Each blood sample will be taken in duplicate, meaning that a repeated sample will be taken from each subjects with a lag time of two days for every time point. Thus, in total 6 blood samples will be drawn during the 9 weeks of the study: t=1, t=3; t=19, t=21; and t=61, t= 63days (table 3). Blood will be drawn by venapunction. Luteine will be measured using high performance liquid chromatography (HPLC). 10% of all plasma measurements will be performed in duplicate, and all samples of a subject will be analyzed in a single session.

Zeaxanthin serum concentration can be seen as a control for compliance concerning the dietary guideline to avoid lutein-rich foods, as lutein and zeaxanthin are found in a stable ratio in foods, whereas zeaxanthin is not part of the test beverage.
Zeaxanthin will be measured using high performance liquid chromatography (HPLC).

Secondary outcome

At the end of the study a short questionnaire will be filled in by the volunteer to ask about the product they consumed.

Body weight and length

Body weight and length will be measured at the start and at the end of the study the bodyweight will be measure to assure no difference in bodyweight.

Plasma lipids

Plasma cholesterol levels will be measured after the washout period (day21) and at the end of the treatment (day 63) to investigate if the lutein-enriched egg-yolk containing beverage had no effect on blood cholesterol levels when consumed for 35 days. In an earlier study it was suggested that one egg/day increases blood cholesterol levels after 12 weeks, which was not observed when the egg-yolk was incorporated into a milk containing beverage.

Study description

Background summary

Age-Related Macular Degeneration (AMD, both wet and dry form) is a degenerative eye disease and the leading cause of irreversible visual loss in the elderly (> 60years) in the Western world. This disease of the elderly robs them of central vision in one or both eyes. People who are affected by AMD have problems reading, driving and performing activities that require clear central vision (Bernstein Paul, Bhosale Prakash et al. 2008). Recent studies have estimated the current prevalence of AMD from around 1.47% (Friedman, O'Colmain et al. 2004) in the United States, to as high as 3.5% in United Kingdom (Wang, Rochtchina et al. 2007). More than half of the registered blindness (54.5%) is due to degeneration at the macula.

Macular pigment is composed primarily of the xanthophylls lutein and zeaxanthin, members of the carotenoid family. The current believe is that lutein and zeaxanthin can help in the prevention of AMD by absorbing blue light and protecting the retina from oxidative stress by neutralizing free radicals (Landrum, Bone et al. 1997; Bernstein, Khachik et al. 2001; Landrum and Bone 2001; O'Connell, Neelam et al. 2006). Epidemiological evidence indicates that a higher intake of lutein and zeaxanthin is associated with a lower risk on AMD

(Moeller, Parekh et al. 2006).

Eggs are among other foods an important source of lutein. Moreover, it is possible to increase the natural lutein concentration in egg yolk (lutein-enriched eggs =>macular eggs) (Thielen Wilhelmus Johannes, Berendschot Toussaint Theresia et al.), which creates opportunities to further increase lutein intake when needed, as has been suggested for subjects suffering from age-related macula degeneration (AMD).

In earlier studies, it has been proven that the lipid matrix of the egg yolk is a vehicle for the efficient absorption of dietary lutein (Granado, Olmedilla et al. 2003; Chung, Rasmussen et al. 2004; Leeson and Caston 2004; Calvo 2005) and that it is possible to increase serum/ plasma levels of lutein and macula lutein levels (Bone, Landrum et al. 1997).
Plat et al. showed in a pilot study (ClinicalTrials.gov Identifier: NCT00527553) with healthy subjects that the consumption of lutein-enriched eggs indeed increased plasma and macular levels of lutein when compared with consumption of regular eggs (not yet published data, NWO-2010, voedings-dagen and personal conversation). In that study they also evaluated the changes in plasma and macular lutein concentrations when the egg was eaten boiled or when the egg yolk was incorporated into a beverage, based on buttermilk.

However, this fresh lutein-enriched egg yolk beverage has a quite limited shelf life of about two to three weeks (NIZO, product report E2010/089). Drying this fresh beverage can extent shelf life, however, this should be performed without loosing the functional properties concerning lutein bioavailability. The effect of pasteurization, spray- and freeze-drying egg-yolks with respect to xanthophyll stability has recently been investigated (Wenzel, Seuss-Baum et al. 2010). It was shown that freeze-drying as well as spray-drying (to 98.9% of dry matter) resulted in a increased concentration per gram egg-yolk compared to either fresh or pasteurized egg-yolks. Authors suggest this to happen, possibly by an irreversible denaturation of the egg-yolk lipo-proteins, resulting in an increased release of xanthophylls that had not been accessible for extraction previously (Wenzel, Seuss-Baum et al. 2010).

The question remaining is, whether lutein bioavailability (increase in lutein serum concentration) is affected by the different drying procedures.

Study objective

The primary objective of this study is to investigate whether consumption of a dried lutein-enriched egg-yolk containing beverage significantly increases serum lutein concentration in healthy volunteers.
A secondary objective is to investigate whether the bioavailability of lutein from a lutein-enriched egg-yolk containing beverage is comparable to its dried version(s).

Research questions
Specific research questions for this proposal are:
1)Does the consumption of a dried lutein-enriched egg-yolk containing beverage significantly increase serum lutein concentration in healthy volunteers?
2)Is the increase in lutein serum concentration from the dried re-suspended lutein-enriched egg-yolk containing beverages comparable to the fresh beverage?
3)Is the consumption of the dried lutein-enriched egg-yolk containing beverage well-accepted in healthy volunteers?

Study design

To answer the research questions the study will have a parallel design with four groups of 25 subjects, consuming either the *plain* control beverage, the fresh lutein-enriched egg-yolk beverage or two differently dried lutein-enriched egg-yolk beverages for 6 weeks. (see also appendix 1)

All participants will start with a three weeks run-in period on a diet low in lutein, as usually is done when studying lutein and other carotenoid serum concentrations. During the whole study (run-in and intervention), subjects will be asked to avoid lutein-rich vegetables and fruits (see Table 2). Furthermore, no vitamin capsules are allowed during the whole study period.

After the run-in period, subjects will randomly assigned to either one of the four groups, stratified for age and gender, for an additional 6 weeks. Blood will be sampled at in total 6 different time points during the study, before and after the run-in period, and after 6 weeks of interventions, at two different in duplicate. The technician will be blinded for the lutein analysis.

Intervention

The study will start with a three weeks run-in period for all participants, as usually has been done when studying lutein and other carotenoid bioavailability. During the whole study, subjects will be asked to avoid lutein-rich vegetables and fruits such as spinach, broccoli, peas (see table 1 for the top 10 contributors to lutein intake in the Netherlands). No vitamin capsules are allowed during the whole study period for the whole study period of 9 weeks. After three weeks of run-in, subjects are randomly assigned to one of the four groups
N Treatment
Control 25 *plain* beverage/ placebo
Treatment 1 25 fresh lutein-enriched egg-yolk beverage
Treatment 2 25 Dried-1 lutein-enriched egg-yolk beverage
Treatment 3 25 Dried-2 lutein-enriched egg-yolk beverage
.
Subjects are asked to consume either 1 bottle of 80 ml each day or an equivalent dried version which they need to re-suspended in tapwater, in the

morning between 7 and 9am. Bottles or sachets will be provided every two weeks, and subjects will be asked to return empty bottles or sachets to evaluate the compliance of the volunteers.

Study burden and risks

There are no risks for the participants during the intervention as the consumption of the beverage is not expected to have any associated with any risk. Venapunctures can occasionally cause a local haematoma or bruise and some participants may report pain or discomfort.
There is no direct (health-related) benefit for the participant.

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

age 18-35 years
BMI 18-25 kg/m2
body weight should be stable for >=6 months (with no weight gain/loss > 3 kg)

Exclusion criteria

not willing to discontinue consumption of vitamin supplements
allergic to cow milk / dairy products/ eggs/ egg-rich products
vegetarians
pregnant or breastfeeding women

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	29-04-2011

Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL35596.081.11