Effects of buttermilk with or without lutein-enriched egg yolk on the serum LDL-cholesterol concentration of slightly hypercholesterolemic volunteers

Published: 08-10-2010
Last updated: 04-05-2024

To evaluate whether (I) buttermilk lowers serum LDL-cholesterol concentrations and as such (II) can prevent the serum LDL-cholesterol raising effects of eggs.

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

Summary

ID

NL-OMON38303

Source
ToetsingOnline

Brief title
buttermilk and cholesterol

Condition

- Other condition

Synonym
hypercholesterolemia

Health condition

cholesterol metabolisme

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,newtricious

Intervention

Keyword: buttermilk, cardiovascular disease, cholesterol, nutrition

Outcome measures

Primary outcome

Measurements will be performed during the run-in period (days 0, 11 and 14) and during the experimental period (days 56, 95 and 98). The main effects (egg-yolk and buttermilk consumption) will be calculated as the absolute differences between values obtained at the end of the experimental (average days 95 and 98) and run-in (average days 11 and 14) periods. The primary endpoint is the change in serum LDL-cholesterol concentrations.

Secondary outcome

Secondary endpoints are changes in serum total and HDL cholesterol, triacylglycerol, apoA-I, apoB and hsCRP concentrations.

In addition, we would like to determine, via DNA analysis, polymorphisms in genes that play a role in (LDL) cholesterol metabolism, such as genes coding for the LDL receptor, PCSK9, SRBI, HMG-CoA reductase, ApoB and ApoE.

Study description

Background summary

Eggs are a valuable source of lutein. Additionally, it is possible to enrich

eggs with lutein, which creates opportunities to further increase lutein intake when needed, as has been suggested for subjects suffering from age-related macula degeneration (AMD). Indeed, we have already shown in our pilot study (MEC 07-1-127) with healthy volunteers that consumption of lutein-enriched eggs increased plasma and macular levels of lutein when compared with consumption of regular eggs. In that study, the lutein-enriched eggs yolks were provided through boiled eggs or through a beverage based on buttermilk. Both food matrices caused comparable increases in serum and macular lutein levels. Interestingly, the results suggested that the boiled eggs increased serum LDL-cholesterol concentrations as expected, but the egg-yolk enriched buttermilk beverage did not. This unexpected finding suggests that consumption of buttermilk influences cholesterol metabolism. However, that study was not specifically designed to examine the effects of the buttermilk beverage on serum LDL cholesterol.

Study objective

To evaluate whether (I) buttermilk lowers serum LDL-cholesterol concentrations and as such (II) can prevent the serum LDL-cholesterol raising effects of eggs.

Study design

A randomized, placebo controlled factorial 2x2 design. The total study duration will be 14 weeks, consisting of a 2 weeks run-in period and a 12 weeks experimental period. Subjects will be stratified for age, gender and BMI over the 4 experimental groups.

Intervention

During the entire study period, volunteers are instructed to consume a diet according to the Dutch dietary guidelines (35 en% fat (10en% saturated fat), 50-55 en% carbohydrates). During the two weeks run-in period all subjects will use daily at lunch 100 mL skimmed milk. During the 12 weeks experimental period, 30 subjects will continue drinking the skimmed milk (control group), while the second group will consume a low-fat buttermilk, the third group the skimmed milk enriched with egg-yolk, and the fourth group egg yolk incorporated into a low-fat buttermilk based beverage. The egg-yolk will be enriched in lutein. Whole egg consumption (others than provided by us) is not allowed during the entire study. The egg-yolk containing buttermilk beverage will be identical as the one used in the earlier study (MEC 07-1-127) and were well-tolerated, their taste was perfectly accepted and did not cause any side effects.

Following the experimental period, subjects can decide whether they want to participate in a DNA research. For this they can choose to donate blood or

saliva.

Study burden and risks

Before the start of the study subjects will be screened to determine eligibility during two visits of respectively 15 and 10 minutes. During these visits, body weight, height and blood pressure will be measured. In addition, a blood sample (3.5 mL at each occasion) is drawn by venapunction. During the study, subjects will receive a beverage (100 mL), i.e. skimmed milk, buttermilk, skimmed milk + egg-yolk, or buttermilk + egg-yolk. At days 0, 11, 14, 56, 95 and 98 fasting blood samples will be drawn (6 x 20 mL). Thus, during the entire study protocol in total 127 mL (2x3.5 mL + 6x20 mLl) blood will be drawn. Subjects will be asked to fill out a food frequency questionnaire two times and to keep a study-diary during the entire 14 weeks study period. On rare occasions, blood sampling might cause bruises or hematoma. Total time investment for the subjects will be approximately 2 hours and 20 minutes.

In case subjects choose to participate in the DNA research and for this choose to donate 10 mL blood instead of saliva, total blood collection during the whole study will be 137 mL.

Contacts

Public
Universiteit Maastricht

Universiteitsingel 50
6229 ER, Maastricht
NL
Scientific
Universiteit Maastricht

Universiteitsingel 50
6229 ER, Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subjects are asked to fill out a general health questionnaire in between the first and second screening visit. Only healthy subjects will be included. Obviously, the remark healthy only concerns the aspects checked for in the in and exclusion criteria. The inclusion criteria are:
• aged between 18 and 70 years
• fasting serum total cholesterol between 5.5 - 8.0 mmol/L
• fasting plasma glucose <7.0 mmol/L
• BMI between 25 - 30 kg/m2
• non-smoking
• willingness to abstain for the duration of the study from egg consumption

Exclusion criteria

• unstable body weight (weight gain or loss >3 kg in the past 3 months)
• allergic for eggs or egg-rich products
• allergic or intolerant for cow-milk (lactose) based products
• indication for treatment with cholesterol-lowering drugs according to the Dutch Cholesterol Consensus
• use of medication or a diet known to affect serum lipid or glucose metabolism
• active cardiovascular disease (for instance congestive heart failure) or recent (<6 months) event, such as acute myocardial infarction or cerebro-vascular accident
• not willing to stop the consumption of vitamin supplements, fish oil capsules or products rich in plant stanol or sterol esters 3 weeks before the start of the study
• men: consumption of >21 alcohol consumptions a week
• women: consumption of >14 alcohol consumptions a week
• abuse of drugs
• pregnant or breastfeeding women
• participation in another biomedical study within 1 month prior to the screening visit
• having donated blood (as blood donor) within 1 month prior to the screening visit or planning to do so during the study
• impossible or difficult venipuncture as evidenced during the screening visits

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-01-2011
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-01-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC 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	NL33461.068.10