The effect of lutein-enriched-egg beverage on progression of Age-related Macular Degeneration, a randomized trial

Published: 10-08-2009
Last updated: 06-05-2024

To assess whether there is the same increase in macular pigment optical density as in healthy subject and to see if there is any change in visual function after a year of intervention.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Interventional

Summary

ID

NL-OMON33516

Source
ToetsingOnline

Brief title
Effect of lutein-enriched-egg beverage on AMD

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
age related macular degeneration, macula

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Newtricious B.V. (leverd ei drank voor onderzoek om niet),OP-Zuid

Intervention

Keyword: AMD, Egg, Lutein, Macular degeneration

Outcome measures

Primary outcome

Measuring macular pigment optical density, the amount of measurable macular pigment in the macula region. Changes in amount of early macular degeneration signs on fundus photographs (drusen or retinal pigment epithelium changes). Contrast sensitivity.

Secondary outcome

Assessing morphological changes of the retina, visual acuity, plasma lutein and zeaxanthin levels, field of vision, and rod function. Vascular function by means of Intima media thickness, flow mediated vasodilatation, arterial distensibility, and lipid metabolism will also be measured in the course of this trial.

Study description

Background summary

In our pilot study (MEC 07-1-127) we saw an increase in both plasma as macular levels of lutein and zeaxanthin. Current believe is that this increase might help against the further deterioration of the retina seen in age-related macular degeneration (AMD) by scavenging for free radicals and filtering out harmful blue light rays. For the purpose of establishing whether these believes hold some truth, we want now to investigate the effect of lutein and zeaxanthin increase in subject with early signs of AMD on visual acuity, visual field and contrast sensibility. To relate these results to our previous study we will also measure the changes in plasma and macular concentrations of these xanthophylls. Once more we will be using the egg-beverage from the pilot study. These have been proven safe and showed no changes in lipid levels after 3

months of consumption.

Study objective

To assess whether there is the same increase in macular pigment optical density as in healthy subject and to see if there is any change in visual function after a year of intervention.

Study design

This will be a randomized, double blind, placebo controlled, interventional trial. Subjects will be randomized, stratified for gender and age, into two groups (N=50 each) receiving either the intervention product (base on 1.5 yolk of a lutein enriched egg containing 0.921 ± 0.106mg of lutein and 0.137 ± 0.014mg of zeaxanthin per yolk) or a placebo. Subject will be followed for 1 year and will be seen three times for measurements.

Intervention

Daily beverage intake containing either 1.5 yolk from eggs enriched with lutein or a placebo, for 1 year

Study burden and risks

Increased Cholesterol levels, induced by daily egg consumption has to date not shown to contribute significantly to the development of heart disease[29]. To date there are no known risk or potential risk from the consumption of lutein or zeaxanthin [28, 30]. There is however evidence that lutein and zeaxanthin may protect against age-related macula degeneration [1, 31-35].

Subjects will be seen three times with a total of 22 (+ 1 hour screening) hours. Methods used in this trial are commonly used techniques which have been proven safe in either previous trials or clinical practice. Subjects* sight will be limited for the investigated eye for a few hours after every visit because of the use of Tropicamide, this is standard practice at our ophthalmology department with only sporadic, and treatable side effects (acute angle-closure glaucoma in 0.03%). Subjects in the intervention group are expected to show a slower progression of the disease than those in the placebo group. We will be using the same egg-beverage as in the pilot study which showed no changes in lipid levels.

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

- Early signs of AMD on fundus photo (drusen, REP changes)
- 50 years and older
- visus > 0.5
- non-smoker (for at least 2 years)
- clear optical media
- no use of supplementation containing lutein or zeaxanthin
- BMI < 30
- No heart disease

Exclusion criteria

- Diabetes
- Lipid metabolism disease
- Use of statins

- Egg allergie

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:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO Date:	11-08-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-10-2009
Application type:	Amendment
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
ClinicalTrials.gov	NCT00902408
CCMO	NL26882.068.09