Intervention study to assess the effect of daily consumption of a lutein-enriched-egg beverage on maintenance of visual function in subjects with early signs of Age-related Macular Degeneration

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To assess whether there is a change in visual function and status of the retina after a year of intervention in subjects with early signs of Age-related Macular Degeneration.

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

Summary

ID

NL-OMON41009

Source
ToetsingOnline

Brief title
I-TEAM (Intervention Trial in Early Age-related Macular degeneration)

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
Age-related Macular Degeneration, AMD, Macular Disease

Research involving
Human

Sponsors and support

Primary sponsor: Newtricious R&D
Source(s) of monetary or material Support: bedrijf Newtricious R&D

Intervention

Keyword: docosahexaonic acid (DHA), Early signs of AMD, Lutein, Visual function

Outcome measures

Primary outcome

To assess the visual function by Best Corrected Visual Acuity.

Secondary outcome

To assess the visual function by Contrast Sensitivity.

To assess morphological changes of the retina by fundus photography.

To assess Visual performance and experience by questionnaire.

To assess Fundus Auto fluorescence.

To obtain information about both macular pigment density and distribution from

double wavelength Fundus Auto fluorescence is performed at Bonn University.

To measure Macular Pigment Optical Density (MPOD), Plasma lutein and zeaxanthin

levels, and to review a blood safety panel.

To assess dark adaptation at one centre (Manchester University)

To assess Cognitive function by psychometric testing in a subgroup (n=40) in

one centre (Tufts University, Boston, MA, USA).

Study description

Background summary

Visual and cognitive impairment affects nearly one in three to four

community-dwelling elders, and is associated with decreased quality of life as well as increased disability and health care costs. Findings from previous studies suggest that a carotenoid, lutein, which is related to a decreased risk of AMD, may also be important in cognitive function in the elderly. Similarly, DHA has been implicated in the prevention or delay in progression of age-related visual and cognitive decline. This study proposes to evaluate long-term intervention with a dairy based beverage containing eggs which are enriched in a natural way for lutein, zeaxanthin and DHA. This food vehicle has been chosen because of the high bioavailability of lutein contained in eggs.

Study objective

To assess whether there is a change in visual function and status of the retina after a year of intervention in subjects with early signs of Age-related Macular Degeneration.

Study design

The study is a double-blind, randomized, placebo-controlled trial designed to test the effect of a dairy beverage containing lutein and DHA enriched eggs on visual and cognitive function in subjects with early signs of AMD.

Intervention

Dietary supplement: A beverage with lutein, zeaxanthine, and DHA enriched egg.

Study burden and risks

Subjects will be seen four times, once for screening and 3 for subsequent study visits. The 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 ophthalmology departments 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.

Contacts

Public
Newtricious R&D

Rotven 8

Oirlo 5808 AL
NL
Scientific
Newtricious R&D

Rotven 8
Oirlo 5808 AL
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Early AMD (AREDS category 2)
o many small drusen, or
o a few intermediate-sized (63-124 micrometres in diameter) drusen, or
macular pigmentary changes
OR
- Intermediate AMD (AREDS category 3)
o extensive intermediate sized (63-124 micrometres in diameter) drusen, or
o at least one large (>125 micrometres in diameter) drusen or
o geographic atrophy not involving the foveal centre
- men and women age >50 years
- BMI 18-35 kg/m2
- Vision > 20/40 for Snellen visual acuity

Exclusion criteria

- ocular media opacity (severe cataract)
- history of active small bowel disease or resection
- atrophic gastritis

- history of hyperlipidemia or screening values as follows (LDL > 5.33mmol/L or 205mg/dL; triglycerides > 4.52mmol/L or 400 mg/dL)
- hypertension (>150/90 mm Hg)
- diabetes mellitus (if also accompanied by signs of diabetic retinopathy)

Study design

Design

Study phase:	3
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):	13-11-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	02-07-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT01694680
CCMO	NL48013.091.14