Adherence to lifestyle changes for age-related macular degeneration - Pilot Study -

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Pre-pilotfase:To optimize procedures and cost efficiency in the design of the pilot phase, we address the following questions:1. Which systemic factors are most useful to monitor AMD supplement intake?2. Can these factors be measured by finger prick...

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

Summary

ID

NL-OMON54691

Source
ToetsingOnline

Brief title
Lifestyle changes in AMD

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
Age-related macular degeneration, retinal aging/degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Oogheelkunde
Source(s) of monetary or material Support: Uitzicht subsidie door bijdragen van ANVVB;Oogfonds;LSBS;Bartimeus;RSB;CORR,vitamineoprecept.nl (gratis

voedingssuplemmenten AREDS2 formule en Omega 3) en bij de pre-pilot (gratis Eyewise) door Health Benefits 08

Intervention

Keyword: age related macular degeneration, AMD, diet, epidemiology, lifestyle, nutrients, nutrition, retinal aging, retinal degeneration

Outcome measures

Primary outcome

Pre-pilot phase

Changes in biomarkers related to supplement intake, such as macular pigment optical density (MPOD); complement factors; inflammation markers (hsCRP and lipids); oxidative stress parameters (MDA, Nitro-tyrosine, 8-iso-PGF-2a by LC-MS/MS); and changes in AMD nutrients parameters (vitamin E, zinc, copper, lutein, zeaxanthin).

Expected outcome: increase in AMD nutrient levels, decrease of complement levels and oxidative stress. The most promising biomarkers will be incorporated in the pilot study.

Pilot study

The primary outcome would be feasibility and acceptability of the interventions. More specifically:

1) The number (percentage) of participants in the different phases of dietary behaviour change (pre-contemplation, contemplation, preparation, action,

relapse or maintenance) regarding following dietary recommendations.

2) The feasibility of the interventions in increasing the average serum levels

of carotenoids, zinc, DHA, EPA, vitamin D and antioxidant capacity markers.

3) The acceptability of participants and health care providers regarding

dietary counselling (qualitative data).

Secondary outcome

Pre-pilot phase

Finger-prick blood measurements compared to conventional plasma/serum

measurements

Differences in outcome of the intake of AREDS2 compared to EYE-WISE

Pilot study:

1. Changes in macular pigment optical density (MPOD) - complement activation;

2. Changes in visual acuity;

3. Progression of AMD.

Study description

Background summary

Age-related macular degeneration is a frequent eye disease in the elderly affecting the center of retina, i.e., the macula. Despite current treatments for the wet form of this disease, it is still the most frequent cause of blindness in the Western world. The disease is the result of the interplay between genetic and environmental factors such as smoking, unhealthy diet, and lack of physical activity. The current clinical recommendations are aimed towards these lifestyle factors: a healthy diet, no smoking, regular physical exercise, and use of antioxidant supplementation. Although assumed to be low by

clinicians as they feel patients find it difficult to actually alter their lifestyle, the adherence and feasibility to these recommendations in clinical ophthalmology practice is unclear. Individualizing the patients* risk of blindness and lifestyle changes, as well as coaching may positively influence adherence strategies, which are part of effective *Behavioral Change Techniques* (BCTs). This study compares the adherence to these strategies aimed to prevent blindness from AMD through a healthier lifestyle.

Study objective

Pre-pilotfase:
To optimize procedures and cost efficiency in the design of the pilot phase, we address the following questions:

1. Which systemic factors are most useful to monitor AMD supplement intake?
2. Can these factors be measured by finger prick-derived dried blood spots?
3. Does the bioavailability and effect differ between important brands of supplements?

Pilot study:

Primary objective(s):
Perform a pilot study to test feasibility and acceptability, i.e.: whether personal risk profiling and/or coaching can help stimulate conversion and adherence to a healthier lifestyle; patient and physician experience regarding motivational strategies that support adherence to AMD-related clinical lifestyle recommendations.

Secondary Objective(s):
Changes in macular pigment optical density (MPOD); changes in visual acuity; and progression of AMD.

Study design

Pre-pilot phase:
Crossover open label intervention study

Pilot study
Open label randomized clinical trial.

Intervention

Pre-pilot phase:

Included participants: N = 10

Each participant will take supplement A or B for 4 weeks, and, after a wash out of 4 weeks, supplement B or A for 4 weeks.
• Supplement A: The recommended established AREDS 2 formula containing vitamins, minerals and antioxidants: Vitamin C (L- ascorbic acid) 500mg, vitamin E (DL- alpha-tocopheryl acetate) 400 mg, Zinc (zinc sulphate) 25 mg, Copper (Copper gluconate) 2 mg, lutein from Tagetes erecta 10 mg
• Supplement B: Eyewise formula containing vitamins, minerals and antioxidants from plant polyphenols as concentrated extracts: Lutein (pure, free form) 20 mg, Zeaxanthin 1000µg, Bilberry (50mg from a 4:1 extract) 200mg, Blackberry (50 mg from a 4:1 extract) 200 mg, Grape seed(10mg from a 50:1 extract) 500 mg, Riboflavin (B2) 0,7 mg, Zinc 5 mg

Pilot study

Included participants: N = 210

• *Standard recommendations*: The first group (n=70) will receive standard care recommendations (according to Netherlands Scientific Society of Ophthalmology 2014, *Richtlijn Leeftijdsgebonden Maculadegeneratie;): refrain from smoking; perform physical exercise regularly; increase the intake of dietary food groups such as green leafy vegetables and fatty fish; and recommendations for supplementation with antioxidants according an established formula and omega 3.

• *Standard recommendations + Risk profiling*: The second group (n=70) receives standard recommendations plus personalized risk profiling. A risk scoring based on currently available prediction tools will be used to determine personalized risks of conversion to late AMD and the potential gain from lifestyle improvement. Individuals will be informed about their own risk profile and a personalized strategy will be communicated.

• Standard recommendations + Risk profiling + coaching*: The third group (n=70) receives standard care (see 1); personalized risk profiling (see 2); plus coaching. A coach will employ behavioral change techniques (BCT) to enhance adherence using motivational interviews, feedback on behavior; and focus on the advantages of following recommendations.

Study burden and risks

Pre-pilot phase

Participation in the study does not carry risks that exceed regular care. The diet, anti-oxidant supplementation and lifestyle recommendations have been accepted as clinical guidelines for AMD. The burden for participants is mainly to undergo regular blood draws, to collect whole blood samples on paper (known as dried blood spot (DBS)) MPOD measurements and to fill in an online food questionnaire. Participants will not be paid for their participation.

Pilot study

This is a pilot study with standard clinical measurements in opthalmologic practices. Participation in the study does not carry risks that exceed regular patient care. Pupil dilation are a potential burden but is necessary to view the posterior segment of the eye. Side effects of these drops include photophobia and reduced accommodative power during 2 hours. The diet, anti-oxidant and omega 3 supplementation and lifestyle recommendations have been accepted as clinical guidelines for AMD. The burden for patients is mainly to participate in the study with regular check-ups, to take dried blood spot assessment (dbsa) in 20µL Mitra tip and/or collecting feces. Patients will not be paid for their participation. Important benefits of participating in this study include three free eye examinations, referral to an ophthalmologist if necessary, and lifestyle advice to prevent or reduce AMD.

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Pre-pilot phase
Inclusion criteria:
1. Eligible to take two AMD supplements for 4 weeks each,
Piot study:
1. Age: 55 years and older
2. Diagnosis: Early/intermediate AMD (based on fundus photographs; Rotterdam criteria: stage 2&3; AREDS criteria: category 2 and 3A), or unilateral late AMD

Exclusion criteria

Pre-pilot phase:
Subject who have a history of AMD or other systemic disease will be excluded from participation in this study,
Pilot study:
1. Participation in other intervention studies for AMD
2. Living in retirement homes (difficulty in implementation of diet)
3. Diagnosis of dementia (because of unreliable dietary recall)
4. Persons with macular pathology other than AMD hindering appropriate grading of the macula
5. Persons diagnosed with late stage AMD in both eyes
6. Persons who are illiterate and have no independent trusted person with them to explain the informed consent form.
7. Persons diagnosed with liver and kidney insufficiency.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2018
Enrollment:	220
Type:	Anticipated

Ethics review

Approved WMO Date:	05-07-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-04-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL65052.078.18