Detection of functional and structural changes in early age related macular degeneration, FUSA - study (FUnctional and Structural changes in Age related macular degeneration)

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A pilot study to prove the validity of the Macubit teste, the Macuscope Test, and the measurements of the retina with the OCT, to test for early functional, and structural loss in the central part of the macula in patients at risk for developing...

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

Summary

ID

NL-OMON32825

Source
ToetsingOnline

Brief title
FUSA-study

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
Age related Macular Degeneration, Macular Degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Age related Macular Degeneration, Macubit, Macular Pigments, Optical Coherence Tomography

Outcome measures

Primary outcome

Visual Acuity

Macubit test result, and testing time

Macuscope test result, and testing time

OCT measurements of the retina, RT, OS thickness, PE contour line

Classification of the macula based on stereo fundusphotography

Secondary outcome

Mutual rerlation of the test results and measurements

Study description

Background summary

AMD is the most frequent cause of visual loss in the elderly population. The exudative type of AMD causes severe visual loss in a relatively short period of time, in contrast the dry type of AMD causes a more gradual and less severe loss of visual function. Nevertheless the dry type of AMD is much more frequent than the exudative type. Recently the development of anti-VEGF therapy proved to be a major breakthrough in the treatment of the exudative type of AMD, unfortunately for the dry type of AMD treatment options are less promising. Some studies showed a benefit of the intake of supplements, like anti-oxydants especially Zinc, and omega-3 fatty acids, but to date no convincing evidence exists regarding the efficacy of these drugs.
It is generally accepted that before visible changes can be detected in the eye, and before functional loss can be registrated with standard examinations,

subtle changes occur in the macula leading to visual disturbances, ultimately leading to visible lesions, like drusen, pigment epithelium changes, atrophy, and functional loss, with small, central relative or absolute scotomas.
Perhaps treatment in this early phase can prevent ongoing damage. This prevention would need an identification of these patients at risk. New tests have been developed for this purpose, the Macubit en the Macuscope tests, and these tests should be validated.

Study objective

A pilot study to prove the validity of the Macubit teste, the Macuscope Test, and the measurements of the retina with the OCT, to test for early functional, and structural loss in the central part of the macula in patients at risk for developing manifest AMD, and the mutual relationship between these tests.

Study design

This is a pilot study, designed as a prospective observational study.
Patients will undergo: visual acuity test, slitlamp examination, fundus photography, OCT, the Macubit test, and the Macuscope test.
The Macubit test the visual field in the central 4 degrees of the macula. The Macuscope measures the amount of macular pigments, the OCT measures the differenr layers of the retina. The fundus photography will enable a classification of the macula of the patients.
Results of these tests will be evaluated, comparing patients with visible early signs of AMD, with controls without visible changes.

Study burden and risks

Time involved in performing the tests is the only burden, with the exception of the temporary discomfort caused by the mydriatics given.

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 > 45 years
Visual acuity 20/30
Clear ocular media
Willing to read the informed consent, and, following reading the information, to sign it.
Refraction between S+3 and S-5

Exclusion criteria

Diabetes Mellitus
Other eye disease, like glaucoma, uveitis, known or identifiable at screening

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL23960.018.08