

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

Published: 08-09-2008

Last updated: 06-05-2024

A pilot study to prove the validity of the Macubite test, 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, Macubita, Macular Pigments, Optical Coherence Tomography

Outcome measures

Primary outcome

Visual Acuity

Macubita 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 relation 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-oxidants 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 registered 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 Macubite and the Macuscope tests, and these tests should be validated.

Study objective

A pilot study to prove the validity of the Macubite test, 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 Macubite test, and the Macuscope test. The Macubite test the visual field in the central 4 degrees of the macula. The Macuscope measures the amount of macular pigments, the OCT measures the different 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

Public

Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland

Scientific

Academisch Medisch Centrum

Meibergdreef 9

1105 AZ Amsterdam
Nederland

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