Aqueous Humor and Imaging Analysis from DME, nAMD and Cataract Patients

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

Summary

ID

NL-OMON54963

Source
ToetsingOnline

Brief title
ACDC study

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
diabetic macular edema, exsudative macular degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: F. Hoffmann-La Roche Ltd ,Hoffmann-La Roche

Intervention

Keyword: Aqueous Humor, Biomarker, Diabetic macular edema, Exudative Macular Degeneration

Outcome measures

Primary outcome

* To establish values for AH biomarker composition in participants with nAMD or DME

Secondary outcome

* To establish normative baseline values for AH biomarker composition from cataract participants undergoing surgery with no vision impacting retinal pathology

* Establish clusters of differentially expressed (vs healthy) AH biomarkers by pathways, including but not limited to angiogenesis, inflammation, apoptosis and fibrosis

* To identify and segment disease phenotypes and grade disease severity in DME / nAMD patients from their multi-modal imaging

* To utilize advanced analytics to correlate AH biomarker signatures with disease morphology, disease phenotypes and severity

* For treatment naïve patients: associate longitudinal AH and imaging biomarkers to model and predict treatment response

* To explore correlations between disease, disease status, treatment response and disease relevant genetic polymorphisms

Study description

Background summary

In patients with exsudative macular degeneration, abnormal blood vessels form in the macula (the location of the sharpest vision of the retina). These leak more than normal blood vessels, which can lead to leakage and swelling. If the abnormal blood vessels are left untreated, scar tissue will form in the macula. All of these factors are associated with a deterioration in vision.

Diabetic macular edema can develop as part of retinal damage from diabetes mellitus. The high blood sugar levels damage small blood vessels, making them more permeable. As a result, leakage and swelling in the macula can also occur, which can lead to visionloss.

By collecting biomarkers, the underlying disease (diabetic macular edema and wet macular degeneration) can better be understood.

Study objective

The aim of this research is to study several important biomarkers of patients with diabetic macular edema and exsudative macular degeneration. Biomarkers are biological characteristics in the body (such as substances, structures and processes) that can be determined to investigate the course, treatment of the disease and how the body responds to treatment. Examples of biomarkers are proteins in the blood, expression of genes (DNA), and certain characteristics in imaging studies. These biomarkers are compared with biomarkers of cataract patients.

Biomarkers are obtained from aqueous humour and blood, an attempt is made to link them to biomarkers of the retinal images. Hereby, the underlying condition can be better understood and a tailor-made treatment can be developed. In addition, these data may lead to the discovery of new proteins or other biomarkers that are important in these conditions, leading to the development of new treatments.

Study design

It is an observational study.

Study burden and risks

There will be one visit of approximately 2 hours. For treatment-naïve patients, there will be two visits of approximately 2 hours.
A paracentesis will be performed. Complications due to this procedure are rare.

Furthermore, one bloodsample will be collected.

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

1. Able and willing to provide written informed consent. Alternatively, a legally authorized representative must be able to consent for the patient.
2. Participants where sampling of >90 µl of AH seems feasible and safe in the opinion of the investigator.
3. Male and female participants aged *18 years for DME participants or * 50 years for nAMD participants or aged * 45 years with age-related cataract (scheduled for cataract surgery)
4. Clear ocular media and adequate pupillary dilation to allow acquisition of good quality retinal imaging

5. DME and nAMD patients with treatment naïve, or ongoing treatment with anti-VEGF

Exclusion criteria

1. Ocular history of retinal (focal-, pan- or macular) laser photocoagulation within the last 3 months in study eye (in AMD: participants with a history of central macular laser photocoagulation in the study eye are not permitted)
2. History of laser iridotomy or YAG laser capsulotomy within the last month in study eye
3. History of vitreoretinal surgery/pars plana vitrectomy in study eye
4. Uncontrolled glaucoma or ocular hypertension * 25 mmHg in study eye
5. Neovascularization of the iris at screening in study eye
6. Participants affected by any systemic autoimmune disease

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-03-2022
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	17-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2021
Application type:	Amendment
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	NL74634.018.20