Identifying progression of retinal disease in eyes with NPDR in diabetes type 2 using non-invasive procedures.

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To identify eyes that show worsening and disease progression (progressor phenotypes). Primary ObjectiveTo identify *progressors* in retinal vascular disease and central retinal edema in type 2 diabetic patients with early NPDR, based on retinal...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON36161

Source
ToetsingOnline

Brief title
ECR-RET-2010-02

Condition

- Diabetic complications
- Ocular haemorrhages and vascular disorders NEC

Synonym
diabetes related eye disorder, non-proliferative diabetic retinopathy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: fundusphotography, NPDRP, Optical coherence Tomography (OCT), Type 2-Diabetes

Outcome measures

Primary outcome

To identify *progressors* in retinal vascular disease and central retinal edema in type 2 diabetic patients with early NPDR, based on retinal disease progression from baseline to the 12-month visit, the following biomarkers will be assessed:

* Microaneurysms turnover (MA formation rate more than 2, i.e. number of new MA from baseline to the 12-month visit) computed from color fundus photographs using the RetmarkerDR software; and

* Retinal thickness increase in eyes with retinal thickening (Increase in retinal thickness above normal range) in the central subfield, the inner ring and/or the outer ring Constantly Present, Present or Absent (as measured by OCT and considering the macula thickness normative data, annex 18.4).

Secondary outcome

To identify correlations between *progressors* and study outcomes in order to characterize eyes/patients that show worsening and are candidates for relatively short term trials of early NPDR. The following study outcomes will be assessed:

* MA turnover (MA formation and disappearance rates);

* retinal thickness changes in the central subfield; the inner ring and/or the outer ring;

* BCVA changes;

* ETDRS step changes; and

* rescue treatment (laser)

Study description

Background summary

The rate of progression of diabetic retinopathy varies widely between different patients, even with similar metabolic control [Cunha-Vaz, Prog Retin. Eye Res. 2005]. It is becoming clear that a large percentage of patients with mild NPDR will take a long time to develop any sight-threatening complication. The inclusion of eyes/patients in a clinical trial that do not show any significant worsening during the period of the trial masks any beneficial effect of the drug being tested. It appears that the only option is to identify the eyes/patients that show progression of retinopathy during a pre-trial run-in period and only include such patients. Characterization of progressor phenotypes in the early stages of diabetic retinopathy and identification of biomarkers of disease progression are also objectives of major interest.

Study objective

To identify eyes that show worsening and disease progression (progressor phenotypes).

Primary Objective
To identify *progressors* in retinal vascular disease and central retinal edema in type 2 diabetic patients with early NPDR, based on retinal disease progression from baseline to the 12-month visit.
Secondary Objective(s)
To identify correlations between *progressors* and study outcomes in order to characterize eyes/patients that show worsening and are candidates for relatively short term trials of early NPDR.

Study design

Observational study with a follow-up at 0, 3, 6 and 12 months in eyes with mild NPDR with: laboratory tests (HbA1C levels), vital signs assessment (Blood Pressure), color fundus photography, retinal thickness and BCVA.
Color fundus photographs will be analyzed with the RetmarkerDR software for the automated assessment of microaneurysms turnover (MA formation and disappearance rate).

Retinal thickness will be measured with Frequency Domain Optical Coherence Tomography (FD-OCT).
Patients who signed informed consent will be evaluate for eligibility at screening. If patient*s eligibility is confirmed, patients will be included in the study and followed for the next 12 months.
Only one eye per patient will be considered for the study (Study Eye). If both eyes meet the inclusion criteria the study eye will be chosen alternatively by selecting the Right or the Left eye.

Study burden and risks

Within this study eyes will be examined with non-invasive methods. Besides the burden of the time it takes to examine the patient, there are no other risks involved.
Mydriatic drops will be instilled that can temporarily cause a slight decrease in vision.

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

Diabetes Type 2 according to 1985 WHO criteria, Age between 35 and 75 years, mild non-proliferative diabetic retinopathy (levels 20 or 35 based on the ETDRS criteria) 7 field color fundus photography, Presence of at least 1 microaneurysm in the central 3000 micrometer area (corresponding to 2 DA) Field 2, Best corrected visual acuity better than or equal to 75 letters (20/32), Refraction with a spherical equivalent less than 5 Dp, Informed consent

Exclusion criteria

Cataract or other eye disease that may interfere with fundus examinations, Glaucoma, Any eye surgery within a period of 6 months, other retinal vascular disease, previous laser therapy, dilatation of the pupil < 5 mm

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2011
Enrollment:	20
Type:	Actual

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
ClinicalTrials.gov	NCT01145599
CCMO	NL36004.018.11