# Comparison of the Optos 200Tx non-mydriatic fundus camera and the Topcon TRC-50DX camera for diabetic retinopathy evaluation

Published: 01-12-2011
Last updated: 30-04-2024

Primary Objective: To compare the quality of fundus photographs taken by (1) the Optoscamera in miosis and (2) the current camera in mydriasis.Secondary Objective: To compare the quality of fundus photographs taken by (1) the Optoscamera in miosis...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Ocular haemorrhages and vascular disorders NEC |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON35208

**Source**
ToetsingOnline

**Brief title**
Evaluation of the Optos 200Tx non-mydriatic fundus camera

### Condition

- Ocular haemorrhages and vascular disorders NEC

**Synonym**
diabetes mellitus

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Diabetic retinopathy screening, Fundus camera, non-mydriatic, Optos

## Outcome measures

### Primary outcome

Main study parameter/endpoint

The number of diabetic lesions found on the Optos 200Tx photographs taken in

miosis, on the Optos 200Tx photographs taken in mydriasis, and on the

photographs made with the current camera in mydriasis.

### Secondary outcome

Secondary study parameters/endpoints

A forced choice subjective ranking of the image quality of paired Optos

pictures:

miosis versus mydriasis.

# Study description

### Background summary

Routine diabetic retinopathy screening is a must for every diabetic patient. To assess the
entire fundus properly, mydriasis (pupil dilatation) is required. After pupillary dilatation fundus
photographs are taken or fundoscopy is performed by an ophthalmologist. Dilatation of the
pupils causes blurred eyesight for at least three to four hours. The eyesight is impaired to an
extent where we advise patients not to drive home themselves. Most patients experience this
as an important burden to the diabetes screening.
The conventional funduscamera we use is the Topcon TCR-50DX. One photograph

captures
45 degrees of the fundus. To photograph the most important parts of the fundus, we need six
photographs. This is done by letting the patient look in different directions and then taking the
pictures.
A new fundus camera has been developed which abolishes the need for mydriasis. The
Optos 200Tx funduscamera captures detailed pictures through a narrow pupil. The second
advantage is the fact that the 200 central degrees of the fundus are photographed at once.
The comparison between a standard 45 degrees camera and the Optos has been conducted
on a large scale in the Reykjavik study (1). The point of interest was assessing the presence
and grading of macular degeneration with both cameras. A 96% agreement between both
cameras was found.
In this study we will compare the number of micro aneurysms and other small diabetic
lesions detectable on the photographs. If the smallest lesions are detectable, the larger
lesions will evidently be seen also. If we find that the quality of the photographs is equal to
the current camera, we could replace the current camera with the Optos 200Tx camera. This
would abolish the need for mydriasis in diabetic screening, and the need for taking six
pictures, saving both time, money and abolishing the burden of mydriasis for patients. If we
find that the performance of the Optos camera is worse than that of the current camera, this
might indicate either differences between miosis and mydriasis or between the Optos and the
current camera. Therefore we also plan to take photographs in mydriasis with the Optos.

**Study objective**

Primary Objective: To compare the quality of fundus photographs taken by (1) the Optos
camera in miosis and (2) the current camera in mydriasis.

Secondary Objective: To compare the quality of fundus photographs taken by (1) the Optos
camera in miosis and (2) the Optos camera in mydriasis (taking pictures in

miosis with the
current camera is not feasible).

### Study design

Cross-sectional observational study in a clinical setting, the outpatient department of the
department of Ophthalmology, UMCG. We will include patients during 3-4 months.

### Study burden and risks

There are no risks associated with participation.
There are no benifits associated with participation.
The only burden associated with this study is that the patient is having to spend an additional 5 minutes in our out-patient clinic.

## 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

We are particularly interested in patients without diabetic retinopathy (DRP) (n=30) and patients with minimal changes due to DRP (micro-aneurysms and other small lesions) (n=30). If the quality of the
pictures is good enough to spot these small lesions, it will also be good enough to spot larger abnormalities.

### Exclusion criteria

Age below 18 years. Absence of informed consent

## Study design

### Design

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| 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

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 06-12-2011 |
| Enrollment: | 30 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 01-12-2011 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 | NL38314.042.11 |