The quality and applicability of smartphone assisted and handheld fundus photography, compared to standard fundus photography.

Published: 25-07-2012
Last updated: 30-04-2024

Assess the quality and applicability of smartphone assisted and handheld fundus photography, compared to standard fundus photography. Photographs will be taken in non-mydratic and mydriatic conditions.

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

Summary

ID

NL-OMON37686

Source
ToetsingOnline

Brief title
Fundus Photography Trial

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
glaucoma, ocular hypertension ; diabetic retinopathy, suger disease related 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: Fundus photography

Outcome measures

Primary outcome

The quality the images will be assessed on a 5 point scale.

In glaucoma an diabetic retinopathy patients we will assess to which extent the

retinal pathology can be assessed based on the taken image.

These parameters will be compared between the different fundus photography

devices.

Secondary outcome

not applicable

Study description

Background summary

Fundus photography is an important tool to detect ocular pathology in a screening setting. With fundus photography, one can visualize the optic disc, the macula, the posterior pole and the retina with its vascularization. Fundus photography is also valuable in the follow up of ocular diseases like glaucoma and diabetic retinopathy.

Most fundus cameras are heavy and not very portable. In addition, the instruments are often fairly expensive. A smaller, more portable and cheaper device with a good image quality would be more practical for routine use or tele-imaging. It would also be good for screening in rural areas. A combination of a smaller size, low costs and good quality would be ideal.

We want to assess the quality and applicability of smartphone assisted and handheld fundus photography, compared to standard fundus photograph. Image

quality is a very important factor for the diagnostic capability of fundus photography. With new available portable fundus photography approaches to make fundus photography better accessible, the question rises what the quality is of the images compared to standard fundus photography. Another aspect is the ability of these devices to detect retinal pathology. Therefore we propose to compare the photographs taken with portable fundus photography with standard fundus photography, to assess both the quality of the images taken with these devices and the value for the clinical practice. Photography will be done under non-mydriatic and mydriatic conditions.

Study objective

Assess the quality and applicability of smartphone assisted and handheld fundus photography, compared to standard fundus photography. Photographs will be taken in non-mydratic and mydriatic conditions.

Study design

Single center cross-sectional study involving healthy persons, glaucoma patients and diabetic retinopathy patients.
After signing informed consent, the participants will undergo fundus photography with the different fundus photography devices. Age, gender, ocular disease, refraction and intra ocular pressure will be recorded.

Study burden and risks

Participants of this study will not be exposed to invasive methods. The study will require time of the patients. Furthermore mydriatic drops will be instilled that can temporarily cause a slight decrease in vision. In rare cases an allergic reaction can occur, which can temporarily cause redness of the eye.

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

Healthy persons
* 18 years of age or older
* Willing and able to sign the informed consent, after reading the information form
* No history of ophthalmological disease;Glaucoma patients
* 18 years of age or older
* Willing and able to sign the informed consent, after reading the information form
* Presence of glaucoma;Diabetic retinopathy patients
* 18 years of age or older
* Willing and able to sign the informed consent, after reading the information form
* Presence of diabetic retinopathy

Exclusion criteria

For all participants
* Media opacities, like cataract, that will make it impossible to make reliable images.
* Hypermetropia more than S+5 dioptres, or myopia more than S-8 dioptres

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:	Recruitment stopped
Start date (anticipated):	27-07-2012
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	25-07-2012
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	NL40163.018.12