Smartphone enabled device for remote ophthalmological evaluation

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Study part 1A) To determine specificity and sensitivity of diagnosis of anterior ocular pathology with the smartphone enabled device, as compared to in-clinic slit-lamp and tonometry examination (gold standard).B) To determine ease of use of the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anterior eye structural change, deposit and degeneration
Study type	Interventional

Summary

ID

NL-OMON54852

Source
ToetsingOnline

Brief title
Smartphone enabled device

Condition

- Anterior eye structural change, deposit and degeneration

Synonym
anterior segment ocular disorders / corneal disease

Research involving
Human

Sponsors and support

Primary sponsor: Melles Hoornvliesskliniek
Source(s) of monetary or material Support: gefinancierd vanuit de Melles Hoornvliesskliniek

Intervention

Keyword: anterior segment ocular pathology, teleophthalmology

Outcome measures

Primary outcome

- True or false anterior segment diagnostics

- Prediction of emergency visits yes/no

Secondary outcome

- Image quality of device and precision and accuracy of eye pressure

measurements

- Ease of use, short term

- Reliability of device

- Safety of device

Study description

Background summary

The ocular diagnosis is (largely) based on visual inspection. Hence, by visually inspecting ophthalmic images or video*s, an ophthalmologist may be able to remotely make a proper ophthalmic diagnosis, aptly named teleopthalmology. Additionally, the eye pressure is regularly determined in the clinical setting, which can also potentially be done remotely (via non-contact tonometry).
We have therefore developed the smartphone enabled device. With this tool attached to a smartphone, a patient him/herself (or a relative) can easily make a slit-image or video of the anterior part of the eye. For an eye pressure determination the patient can also make a video, but now while the device directs an air puff at the cornea. The ophthalmologist can then remotely inspect the image and/or video and act/advice accordingly.
However, in order to evaluate ease of use both for the patient and the ophthalmologist, and to establish its diagnostic sensitivity and specificity as compared to in-clinic diagnostics, clinical trials must be performed.
We believe that remote eye diagnosis with the device will improve

(cost) efficacy of ophthalmic services, facilitate timely referrals and increase patient safety.

Study objective

Study part 1

A) To determine specificity and sensitivity of diagnosis of anterior ocular pathology with the smartphone enabled device, as compared to in-clinic slit-lamp and tonometry examination (gold standard).
B) To determine ease of use of the device over a short (days) period of time.

Study part 2

A) To determine whether specificity and sensitivity of the device in predicting necessary emergency visits during a short post-surgery is better than phone calls only, as determined afterwards by in-clinic examination (gold standard).

Study design

Part 1: crossover trial (and short-term beta test).
Part 2: controlled trial.

Intervention

During the trial the smartphone enabled device will be used for diagnostics.

Study burden and risks

Patients will have to use the smartphone enabled device, which is a slight time burden (about an hour total). Risks are minimal, as regular clinic visits continue during the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Presence of anterior segment ocular pathology
- 18 years and older

Exclusion criteria

- Younger than 18 years old
- Unable to clearly understand the language used in the clinic (Dutch)
- Unable to clearly understand the use of the smartphone enabled device

Study design

Design

Study type:	Interventional
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):	15-06-2020
Enrollment:	185
Type:	Actual

Medical products/devices used

Generic name:	Remote anterior segment ocular diagnostics using the smartphone enabled device.
Registration:	No

Ethics review

Approved WMO

Date:	11-06-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	01-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL72311.058.20