Trial Description

Title

Evaluation of innovative OCT techniques in comparison to conventional OCT

Trial Acronym

Evokon

URL of the trial

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Brief Summary in Lay Language

Optical coherence tomography (OCT) is a safe, non-invasive method for high-resolution imaging of the human retina. It uses reflection of light beams projected on the retina to calculate tomographic images.
OCT as an examination entity has been standard of care in retinal diagnostics for over 10 years. In this study, we want to test a new OCT device on top of routine OCT examination. The new OCT device uses the same basic principle, but differs in the mode of light projection and image calculation. This offers the potential for self-examination and possible future home-application of the device by the patient. Whereas established OCT devices rely on attention of a physician or a medical assistant, the new device was designed to be fully operated by the patient alone.
Aim of this study is to test the possibility of self-examination.

Brief Summary in Scientific Language

Aim of this study is to examine Full-Field-OCT as a retinal diagnostic tool in comparison to conventional SD-OCT. FF-OCT is a possible candidate for the construction of low-cost easy-to-use OCT devices that can be administered by the patient himself at home. Our study aims to test imaging quality as well as sensitivity and specificity of detection of pathological findings. We want to evaluate the reliability of OCT self-examination as well as to gather patient feedback.

The target sample size was elevated from 51 to 102 patients by two amendments (15.3.2019 and 23.10.2019).

Do you plan to share individual participant data with other researchers?

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Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013755**
- Date of Registration in DRKS: **2018/03/14**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **A 139/17 , Ethikkommission der Christian-Albrechts-Universität zu Kiel**

Secondary IDs

- EUDAMED-No.
(for studies acc. to Medical Devices act): **CIV-17-12-022384**

Health condition or Problem studied

- ICD10: **H35.3 - Degeneration of macula and posterior pole**

Interventions/Observational Groups

- Arm 1: **Examination of the retina of patients with (suspected) retinal disease with standard OCT and new Full-Field-OCT**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **assessor, data analyst**
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Rate of successful self-measurement after prior instruction from the physician

Secondary Outcome

Grading of OCT images of both devices. The images will be presented in a randomized order without patient identification.
- Grading of image quality
- Sensitivity and specificity in the detection of retinal pathologies, above all intraretinal fluid (IRF), subretinal fluid (SRF), pigment epithelium detachments (PED)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Ophthalmologie, Kiel**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/03/19**
- Target Sample Size: **102**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Persons during ophthalmologic examination requiring myriatic eye drop installation and OCT examination

Exclusion criteria

Inability to give informed consent, mental disability, under 18 years of age, pregnancy/breast-feeding

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2020/03/12**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*