Trial Description

Title

MHz-OCT

Trial Acronym

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URL of the trial

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Brief Summary in Lay Language

The diagnostic device „Megahertz-OCT“ (MHz-OCT) allows high speed imaging based on a novel, fast laser source. The device allows to scan the complete posterior part of the eye (vitreous, retina, choroid) over a large field of view with one single scan. Patients, who require an examination by optical coherence tomography (OCT) based on clinical criteria are elegible to be included in the study. In the study imaging with the novel, fast MHz-OCT is performed in addition to standard OCT imaging.

Goal of the study is to investigate, if fast MHz-OCT imaging offers advantages compared to standard imaging. Analysis of data sets is performed off-line after the imaging session, evaluation of image quality is masked to image source.

Brief Summary in Scientific Language

Optical coherence tomography (OCT) is a key diagnostic imaging modality in ophthalmology today. However, currently available devices are limited by speed of image acquisition. The current study investigates a novel OCT device, „MHz-OCT“, which has been developed at the Institute for Biomolecular Optics (LMU München) based on a novel laser source. MHz-OCT allows a considerably faster image acquisition compared to conventional OCT devices.

Primary goal of the study is to investigate, if the fast MHz-OCT image set after appropriate software processing provides equal or better information compared to standard OCT. Therefore conventional OCT images are compared with additional MHz-OCT images generated from the full 3D datasets. Analysis of MHz-OCTs and masked grading is performed „off-line“, i.e. after the patient visit.

Ths study is performed monocentric at the Department of Ophthalmology, LMU Muenchen Germany. It is scheduled to include a total of 85 patients in the study. Patients are elegible to be included, for whom a conventional OCT examination of the retina is necessary. In the study in addition to standard OCT an one-time additional non-touch examination is performed by MHz-OCT. Clinical management and follow-up is performed by standard clinical practice and is not altered by the study.

Organizational Data

- DRKS-ID: **DRKS00005173**
- Date of Registration in DRKS: **2013/07/26**
- 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.: **192/13 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

- EUDAMED-No.
(for studies acc. to Medical Devices act): **CIV-13-02-009703**

Health condition or Problem studied

- ICD10: **H30-H36 - Disorders of choroid and retina**

Interventions/Observational Groups

- Arm 1: **In patients, who are imaged by standard OCT for retinal changes, additionally MHz OCT is applied.**
- Arm 2: **Current generation standard OCT**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **Single blind**
- Who is blinded: **assessor**
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary endpoint is based on the comparison of OCT images, which are obtained by image analysis from MHz-OCT datasets, with OCT images from current generation OCT systems (e.g. Heidelberg Spectralis SD-OCT). The question to be answered is, if diagnostic quality of images from the fast 3D MHz-data set are equal or better than current standard SD-OCT technology for diseases of the vitreoretinal interface, within the retina and the choroid. Primary endpoint is defined as no difference in diagnostic clinical quality grading (Grading of "clinical diagnostic value") between MHz-OCT and standard OCT.

Secondary Outcome

Sekundary outcomes are the effects of different recording and analysis protocols with MHz OCT for different diseases. Also as an explantory endpoint, potential requirements for the usability of the device are investigated.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **LMU München, Augenklinik, München**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2013/09/01**
- Target Sample Size: **85**
- 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

- **Patients can be included, who need for diagnosis or follow-up a standard OCT**
- **Men and women >18 years**
- **Informed written consent**

Exclusion criteria

General:

•No written informed consent;

•age<18 years;

•pregnancy of breast feeding;

•patients with severely reduced health status;

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Private sponsorship (foundations, study societies, etc.)**

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- **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 ongoing**
- Study Closing (LPLV): **[---]***

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.*