PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Immediate Registration of photocoagulation lesions by slit-lamp adapted optical coherence tomography

Trial Acronym

SoPhoS

URL of the trial

[---]*

Brief Summary in Lay Language

The SoPhoS study investigates fine tissue effects of retinal photocoagulation. It applies a customized machine for optical coherence tomography (OCT). In retinal photocoagulation, 1/50 - 1/5 s short, very intense laser irradations generate fine retinal burns, which are helpful in ischemic retinal diseases such as diabetic retinopathy to protect the eye from consecutive secondary diseases. The customized OCT-machine can record highly resolved sectional images of the coagulating retina in high speed, with hundreds of Frames per second. It also allows conclusions about temperature profiles and Perfusion within the tissue. We can recrute Patient eyes that receive panretinal laser photocoagulation for the first time and that are legally capable to give informed consent (above 18 years old, no prisoners), that are not pregnant and are physically without obstacles for the Treatment. Follow up examinations with clinical Standard Imaging will be necessary after 1 day, 1 and 3 months.

Brief Summary in Scientific Language

The SoPhoS study applies Phase sensitive high-speed OCT to record representative Images of retina and choroid under laser irradatiation. It does not only generate morphological Information via OCT reflecitivity, but also allows conclusions about retinal and choroidal Perfusion, tissue displacement and temperature profiles. Functionality of the method in humans is to be tested, and first conclusions about the clinical potential of the method are to be drawn.

Organizational Data

- DRKS-ID: **DRKS00009350**
- Date of Registration in DRKS: **2015/10/21**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

DRKS-ID: **DRKS00009350**
Date of Registration in DRKS: **2015/10/21**
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.: **D470/15 , Ethikkommission der Christian-Albrechts-Universität zu Kiel**

Secondary IDs

Health condition or Problem studied

- ICD10: **H36.0 - Diabetic retinopathy**
- ICD10: **H34.8 - Other retinal vascular occlusions**

Interventions/Observational Groups

- Arm 1: **Patients with indication for first session of panretinal laserphotocoagulation: Recording with high-speed OCT during application of 40 photocoagulation lesions, afterward clinical imaging of these lesions with OCT and color fundus photo over 3 months.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Histologic tissue changes under retinal photocoagulation

Secondary Outcome

data quality of custom made high-speed OCT

Countries of recruitment

- DE **Germany**

Locations of Recruitment

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

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/09/15**
- Target Sample Size: **20**
- 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

indication for panretinal photocoagulation, first treatment session

Exclusion criteria

pregnancy
disseases that hamper photocoagulation (Tremor, Nystagmus, spine Deformation), corneal diseases

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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  10117 Berlin
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.bmbf.de**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Background literature **Darstellung der analog zur Patientenstudie durchgeführten Tierversuche**

** 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.*