Trial Description

Title

Correlation of subjective visual parameters with morphologic parameters in reactivation of exsudative maculopathies

Trial Acronym

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URL of the trial

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Brief Summary in Lay Language

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Brief Summary in Scientific Language

Different exsudative diseases of the macula (e.g. age related maculopathy (AMD), diabetic macular edema (DME), macular edema in retinal vein occlusion (RVO), myopic choroidal neovascularisation (CNV)) are currently treated by intravitreal injection of VEGF inhibitors. The official recommendations of the german ophthalmological associations (DOG, BVA, RG) include that affected patients shall be controlled in monthly intervals after the end of treatment. These controls require a high logistic support for both patients and examiner (time, transport, devices). The aim of this study is to investigate wether subjective parameters (estimation of the visual acuity and the metamorphopsia) can help to detect reliably a reactivation of disease. For this purpose we plan to compare the current gold standard of clinical examination (visual acuity, morphologic examination with the optical coherence tomography (OCT)) with the above-named subjective parameters. We try to identify patient groups in which the control interval might be adapted. Different diseases (AMD, DME, RVO, myopic CNV) shall be analyzed. In a second step the correlation between subjecitve parameters and morphologic parameters shall be investigated.

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

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Description IPD sharing plan

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Organizational Data

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DRKS-ID: **DRKS00006851**

- Date of Registration in DRKS: **2014/10/09**
- 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.: **413/14 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **non-interventional study**
  retrospective data analysis of all patients who were examined in the clinical "IVOM-OCT-consultation" (clinical control of the success of treatment about 8 weeks after the last intravitreal injection, 4 weeks after the first control of success). If several appointments in the "IVOM-OCT-consultation" have taken place only the first documented appointment will be analysed (analysis of the documented subjective
  estimation of visual acuity and metamorphopsia, analysis of the documented visual acuity, analysis of the executed OCT)

Characteristics

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

Primary Outcome

specificity and sensitivity of subjective parameter (e.g. visual acuity, metamorphopsia; evaluation of the subjective devolopment as defined by better / worse / equal) in the evaluation of activity of maculopathy in age related maculopathy, retinal vein occlusion, diabetic retinopathy and other maculopathies

Secondary Outcome

Differences in specificity and sensitivity of the above-named parameter in different diseases, identification of characteristics of the morphology in reactivated disease, correlation of these characteristics with subjective parameter, correlation with basic data (eye function, age)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Augenheilkunde, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/10/15**
- Target Sample Size: **1200**
- 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

first examination of patients with maculopathy (age related maculopathy, diabetes, retinal vein occlusion, myopia, other diseases with development of choroidal neovascularisation) having received intravitreal injections with anti-VEGF (bevacizumab, ranibizumab, aflibercept) who were adjudged to be not in need of further treatment and were appointed to control examinations in the "IVOM-OCT-Sprechstunde"

Exclusion criteria

examination other than primary examination, other interventions (e.g. injection of TAC, Jetrea, Ozurdex), surgery of the study eye in the intervall between last intravitreal injection and OCT control

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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URL: **[---]***

Status

- Recruitment Status: **Recruiting planned**
- 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.*