Trial Description

Title

Indication for stereotactic radiotherapy of the macula with IRay® for wet age-related macular degeneration

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This study investigates which proportion of patients with active wet age-related macular degeneration an IRay treatment is a treatment option. We will check inclusion and exclusion criteria used (a) in the INTREPID study as well as (b) the official recommendations in Germany.

Brief Summary in Scientific Language

The stereotactic radiation of the macula by means of the IRay-device is an additional option in the treatment of wet age-related macular degeneration (wAMD) besides standard therapy with intravitreal injections of anti-VEGF drugs. The randomized, multicentric double-blind INTREPID-study compared clinical results of patients receiving standard treatment (and sham radiation) with standard treatment and radiation with IRay. The study showed that IRay treatment was efficacious by reducing the number of intravitreal injections by 40-50% within 2 years in a subgroup of patients (limited disease with size of lesion <4mm, macular volume >7.4 mm³). (Sub-)retinal fibrosis was a negative prognostic factor. The authors of INTREPID reported, that IRay treatment might be a valuable treatment option in up to 2/3 of all wAMD patients. However, this contradicts our impression in everyday clinic. That is why this study should evaluate, which proportion of patients might benefit from additional IRay treatment, or for which proportion exclusion criteria are fulfilled.

Organizational Data

- DRKS-ID: **DRKS00009593**
- Date of Registration in DRKS: **2015/11/02**
- 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.: **463/15 , 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: **all patients with wet AMD (age-related macular degeneration) treated within a time frame of 4 months in the hospital are checked for inclusion/exclusion criteria for an IRay treatment**

Characteristics

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

Primary Outcome

Proportion of patients who are eligible for IRay treatment

Secondary Outcome

characteristics of patient eligible for IRay: clinical history (number of treatments within last 6/12 months, number of different drugs, visual acuity before treatment and at time of analysis); description of clinical evaluation (SRT offered/planned/performed/delayed); analysis of patient response to IRay treatment (declined? reasons); description of patients not eligible: reasons (characteristics of AMD, ocular comorbidity, systemic comobidity), was IRay possible at a time before this evaluation? description of clinical course of patients who were eligible before (number of intravitreal injections)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/12/01**
- Target Sample Size: **800**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

wet age related macular degeneration, previously treated with intravitreal injections

Exclusion criteria

none

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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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.*