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

Trial Description

Title

A prospective randomized trial on CellCept© (Mycophenolat Mofetil) in risk penetrating keratoplasty

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Evaluation of CellCept© (Mycophenolat Mofetil) for prevention of graft rejections following risk penetrating keratoplasty.

Brief Summary in Scientific Language

Evaluation of CellCept© (Mycophenolat Mofetil) for preventing graft rejections following risk penetrating keratoplasty.

Organizational Data

- DRKS-ID: **DRKS00000011**
- Date of Registration in DRKS: **2008/09/05**
- Date of Registration in Partner Registry or other Primary Registry: **2006/06/27**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **116/00 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Primary Registry-ID: **NCT00411515 (ClinicalTrials.gov)**
- Partner Registry-ID: **UKF000727 (Register Klinischer Studien des Universitätsklinikums Freiburg)**

Health condition or Problem studied

- ICD10: **H44.5 - Degenerated conditions of globe**
- Free text: **CellCept**
- Other: **5-125: null**

Interventions/Observational Groups

- Arm 1: **The patients of the MMF group receive MMF orally 2x1 g daily for 6 months.**
- Arm 2: **No systemic immunosuppression**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Endpoints were immune reaction free and clear graft survival and the occurence of side-effects

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2000/09/13**
- Target Sample Size: **140**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Keratoplasty with increased risk for immunologic graft rejection in the abscence of other risk factors for graft failure. (repeat keratoplasty, steroid-response, limbo-keratoplasty, oversized graft.

Exclusion criteria

Normal risk cases. Herpes-Keratitis. Glaucoma. Limbus stem cell deficiency.

Addresses

- **Primary Sponsor**

  Hoffmann-La Roche AG

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **http://www.roche.de/index.htm?sid=75386baff8814f375f23a401962a212b**
- **Contact for Scientific Queries**

  Universitätsklinikum Freiburg
  Ophthalmologie
  Mr. Prof. Dr. med. Thomas Reinhard
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Contact for Scientific Queries

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URL: **http://www.uniklinik-freiburg.de/augenklinik/live/homede.html**

Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Hoffmann-La Roche AG
79639 Grenzach-Wyhlen

Telephone: **+49 7624 14-0**
Fax: **+49 7624 1019**
E-mail: **[---]***
URL:
http://www.roche.de/index.htm?sid=74edc683109514942246c4869810032a

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2006/05/01**

Trial Publications, Results and other documents

- Paper **Birnbaum F, Mayweg S, Reis A, Böhringer D, Seitz B, Engelmann K, Messmer EM, Reinhard T. (2009) Mycophenolate mofetil (MMF) following penetrating high risk keratoplasty – long-term results of a prospective, randomised, multicentre study. Eye Nov;23(11):2063-70.**

** 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.*