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

Trial Description

Title

Influence of anterior chamber depth on postoperative central endothelial cell loss after cataract surgery

Trial Acronym

AC-Endothelial cell study

URL of the trial

[---]*

Brief Summary in Lay Language

To extract the lens within cataract surgery it gets emulsified by using ultrasound energy. This is a risk factor for endothelial cells of the cornea and because the procedure leads to endothelial cell loss. To detect a possible influence of the anterior chamber depth on postoperative endothelial cell loss as a possible risk factor, we measured central endothelial cell loss before and three months after surgery. We determined anterior chamber depth before surgery within our preoperative ophtalmological examination.

Brief Summary in Scientific Language

There are different pre- and intraoperative risk factors that lead to endothelial cell loss within cataract surgery. Cell loss is an important parameter, which shows the degree of surgical trauma and is important to determine risk factors. Cataract surgery takes place within a limited space, the anterior chamber. Therefore this region plays a huge role within surgery. The anterior chamber is the space between iris and endothelium of the cornea and limits the surgerons' operating field.
A narrow anterior chamber should lead to greater endothelial cell loss, because the operating field is smaller.
To determine whether the anterior chamber depth is a risk facor for endothelial cell loss we measured the cell density before and 3 months after surgery. We also determined the anterior chamber depth and anterior chamber volume using the Oculus Pentacam®. We additionally measured axial lenth with the IOL Master® which is part of the preoperative routine examination, as a another possible risk factor of ECL.
Secondary parameters where lens densitiy (also determined using the Pentacam®), and best corrected visual acuity.

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

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004939**
- Date of Registration in DRKS: **2013/05/24**
- 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.: **167-2008 , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1142-7613**

Health condition or Problem studied

- ICD10: **H25.8 - Other senile cataract**

Interventions/Observational Groups

- Arm 1: **measurement of lens density, anterior chamber depth, anterior chamber volume, axial length preoperatively**
  measurement of central endothelial cell density pre- and 3 months postoperatively
  visual acuity pre- and 3 months postoperatively

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
-

Study Type: **Non-interventional**

Study Type Non-Interventional: **Other**

Allocation: **Single arm study**

Blinding: **[---]***

Who is blinded: **[---]***

- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

postoperative (after 3 months) central corneal endothelial cell density measured using a endothelial cell microscope

Secondary Outcome

best corrected visual acuity 3 months postoperatively

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/06/21**
- Target Sample Size: **50**
- 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

senile Cataract

Exclusion criteria

previous opthalmological surgery
lens density less than 1900 cellls/ mm2
corneal diseases

Addresses

- **Primary Sponsor**

  Klinik und Poliklinik für Augenheilkunde
  Ms. Dr. Renate Wiedemann
  Liebigstraße 10-14
  04103 Leipzig
  Germany

  Telephone: **03419721650**
  Fax: **03419721659**
  E-mail: **renate.wiedemann at medizin.uni-leipzig.de**
  URL: **http://augenklinik.uniklinikum-leipzig.de/**
- **Contact for Scientific Queries**

  Klinik und Poliklinik für Augenheilkunde
  Ms. Dr. Renate Wiedemann
  Liebigstraße 10-14
  04103 Leipzig
  Germany

  Telephone: **03419721650**
  Fax: **03419721659**
  E-mail: **renate.wiedemann at medizin.uni-leipzig.de**
  URL: **http://augenklinik.uniklinikum-leipzig.de/**
- **Contact for Public Queries**

  Klinik und Poliklinik für Augenheilkunde
  Ms. Dr. Renate Wiedemann
  Liebigstraße 10-14
  04103 Leipzig
  Germany

Contact for Public Queries

Klinik und Poliklinik für Augenheilkunde
Ms. Dr. Renate Wiedemann
Liebigstraße 10-14
04103 Leipzig
Germany

Telephone: **03419721650**
Fax: **03419721659**
E-mail: **renate.wiedemann at medizin.uni-leipzig.de**
URL: **http://augenklinik.uniklinikum-leipzig.de/**

Sources of Monetary or Material Support

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

Klinik und Poliklinik für Augenheilkunde
Ms. Dr. Renate Wiedemann
Liebigstraße 10-14
04103 Leipzig
Germany

Telephone: **03419721650**
Fax: **03419721659**
E-mail: **renate.wiedemann at medizin.uni-leipzig.de**
URL: **http://augenklinik.uniklinikum-leipzig.de/**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/07/31**

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.*