Trial Description

Title

Measurement of intraocular pressure in supine position using a rebound tonometer

Trial Acronym

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URL of the trial

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Brief Summary in Lay Language

**Rebound tonometry is used in our clinic since 2008 for measurement of intraocular pressure.
This method is very useful for measurement of intraocular pressure in children, in difficult
situations and for self-tonometry. No application of eyedrops is needed for this method. At this
moment, the first tonometer using rebound tonometry is available at the market for measurement of intraocular pressure in supine position. The intraocular pressure of 100 glaucoma patients will be measured using the iCare PRO tonometer. To test agreement of the new device with standard methods, intraocular pressure is also measured with the Goldmann applanation, Perkins applanation and the Pascal contour
tonometer. To detect probable confouner test for visual acuity, visual field, corneal pachymetry
are applied.**

Brief Summary in Scientific Language

**Since 2008 we use a new device for intraocular pressure measurement called rebound tonometer
(RBT, iCare, Tiolat Oy, Helsinki, Finnland). The method was first described by Kontiola [1].
For the RBT as a new device in many reports a good correlation of measured pressure values
between the RBT and the Goldmann applanation tonometer (gold standard) was shown. Studies
were done for healthy [2], as well as for glaucoma patients [3,4]. moreover, measurement with the
RBT is a safe method, which is also appliable for children. Another study showed a high degree of
intraobserver and interobserver reproducibility [5]. In comparison to the gold standard method
(Goldmann applanations tonometry), the measurement with the RBT shows slightly higher values
[6-8].
Newly, a rebound tonometer is available for measurement of intraocular pressure**

in supine position. Aim of this study is to measure intraocular pressure in 100 glaucoma patients using the new device. The measurement is performed by the doctor. Additionally, we measure the intraocular pressure using the Goldmann applanation, the Perkins applanation and the Pascal contour tonometer.

References:
1: Kontiola AI. A new electromechanical method for measuring intraocular pressure. Doc Ophthalmol 1997; 93: 265-76.
2: Garcia-Resua C, Gonzalez-Meijome JM, Gilino J, et al. Accuracy of the new ICare rebound tonometer vs. other portable tonometers in healthy eyes. Optom Vis Sci 2006; 83: 102-7.
3: Martinez-de-la-Casa JM, Garcia-Feijoo J, Castillo A, et al. Reproducibility and clinical evaluation of rebound tonometry. Invest Ophthalmol Vis Sci 2005; 46: 4578-80.
4: Sahin A, Niyaz L, Yildirim N. Comparison of the rebound tonometer with the Goldmann applanation tonometer in glaucoma patients. Clin Exp Ophthalmol 2007; 35: 335-39.
5: Sahin A, Basmak H, Niyaz L, et al. Reproducibility and tolerability of the ICare rebound tonometer in school children. J Glaucoma 2007; 16: 185-8.
6: Fernandes P, Dias-Rey JA, Queiros A, et al. Comparison of the ICare rebound tonometer with the Goldmann tonometer in a normal population. Ophthalmic Physiol Opt 2005; 25: 436-40.
7: Martinez-de-la-Casa JM, Garcia-Feijoo J, Vico E, et al. Effect of corneal thickness on dynamic contour, rebound, and Goldmann tonometry. Ophthalmology 2006; 113: 2156-62.
8: Moreno-Montañes J, Garcia N, Fernandez-Hortelano A, et al. Rebound tonometer

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

- DRKS-ID: **DRKS00000581**
- Date of Registration in DRKS: **2010/10/08**
- 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.: **10-146 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **H40.1 - Primary open-angle glaucoma**
- ICD10: **H40.0 - Glaucoma suspect**

Interventions/Observational Groups

- Arm 1: **No intervention, measurement of intraocular pressure with the rebound tonometer**
- Arm 2: **No intervention, measurement of intraocular pressure with the Goldmann applanation tonometer**
- Arm 3: **No intervention, measurement of intraocular pressure with the Perkins applanation tonometer**
- Arm 4: **No intervention, measurement of intraocular pressure with the Pascal contour tonometer**

Characteristics

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

Primary Outcome

EP:
Measurement of intraocular pressure (mmHg) at a particular time using the rebound tonometer
(iCare PRO). Moreover, measurement of intraocular pressure is performed using the Goldmann

**applanation tonometer and the Pascal contour tonometer in seating position and additionally the Perkins applanation tonometer in supine position.
Agreement of the methods is tested by using correlation and Bland-Altman plots.**

Secondary Outcome

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Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2010/10/18**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

patients with glaucoma disease, which want to participate in this study

Exclusion criteria

patients without glaucoma disease

patients, which do not want to participitate in this study

patients, which are not able to give their agreement for the study

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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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.*