Trial Description

Title

STUDY TO PERFORM A CORNEAL MEASUREMENT METHOD FOR THE CATALYS® SYSTEM

Trial Acronym

CMAA-102-OS40

URL of the trial

[---]*

Brief Summary in Lay Language

A CE marked measurement attachment (software and lens device) as part of a laser will be used to measure the corneal astigmatism. During the study only measurements of the cornea without contacting the eye of the patient will be conducted, to determine the steep axis of the cornea before a cataract laser treatment which is not part of the study.

Study objective is to evaluate measurements to determine the steep meridian of the cornea before the laser treatment.

Brief Summary in Scientific Language

The SMRT device is CE marked and measures the steep axis in a non-contact way before the laser treatment. SMRT means Steep Meridian Registration Technology.Subjects who agree to participate will be enrolled in the study upon signing the informed consent. Preoperative baseline evaluation will be compared to the steep meridian measurments.

Organizational Data

- DRKS-ID: **DRKS00007826**
- Date of Registration in DRKS: **2015/02/18**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **5147-14 , Ethik-Kommission der Medizinischen Fakultät der Ruhr-Universität Bochum**

Secondary IDs

Health condition or Problem studied

- ICD10: **Z01.0 - Examination of eyes and vision**

Interventions/Observational Groups

- Arm 1: **The first eye of enrolled subjects shall be measured once with the SMRT device before the Laser treatment.**

Characteristics

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

Primary Outcome

SMRT measurement success rate

Secondary Outcome

non

Countries of recruitment

- DE **Germany**
- AT **Austria**

Locations of Recruitment

- University Medical Center **Augenklinik, Bochum**
- University Medical Center **Augenklinik, Salzburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/03/02**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **22 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

***Male or female at least 22 years of age at the time of preoperative examination**
***At least 0.5 D of corneal cylinder**
***Clear intraocular media, except for the presence of cataract**
***Willing and able to participate in the study**
***Able to fixate**
***Signed informed consent**

Exclusion criteria

***History of prior intraocular or corneal surgery, active ophthalmic disease, or other ocular abnormality in the study eye(s), which in the opinion of the investigator would confound the study results.**
***Evidence of keratoconus or abnormal topography in the study eye(s), which in the opinion of the investigator would confound the study results.**
***Patient is pregnant, plans to become pregnant, is lactating or has another condition associated with the fluctuation of hormones that could lead to refractive changes**
***Concurrent participation or participation within 30 days prior to preoperative visit in any other clinical trial**

Addresses

- **Primary Sponsor**

  OptiMedica Corporation
  Ms. Priya Janakiraman

Primary Sponsor

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Sources of Monetary or Material Support

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

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

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- 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.*