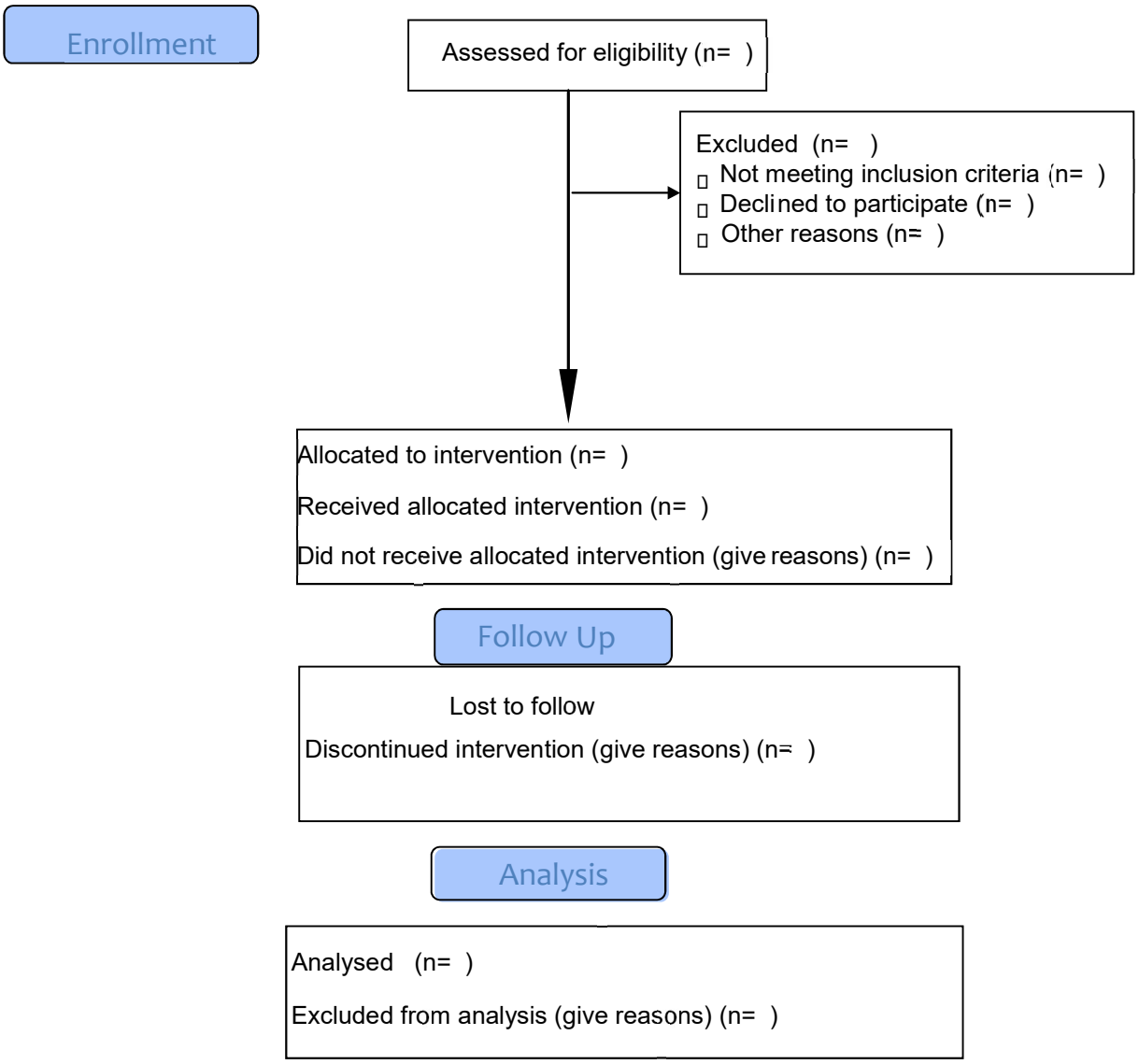
Document Date: May 24, 2019

The Effect Of Preoperative Parameters On Success After Descemet Membrane Endothelial Keratoplasty (DMEK) Surgery

CLINICAL STUDY PLAN

ClinicalTrials.gov Results Data Element Definitions for Interventional and Observational Studies

1. Participant Flow



Groups/Cohorts	Interventions
Cohort All patients	Procedure/Surgery: Descemet membrane endothelial keratoplasty (DMEK) All participants underwent DMEK surgery

Period(s)
Our study was created by planning a 6-month follow-up period. Information about the number of patients at the beginning and end of the study will be reported when the study is completed.

▼ 2. Baseline Characteristics

Patients' age, gender, eye side, additional diseases, medications used and preoperative visual acuity values will be recorded at the beginning of the study.

Groups/Cohorts	Interventions
Cohort All patients	Procedure/Surgery: Descemet membrane endothelial keratoplasty (DMEK) All participants underwent DMEK surgery

Baseline Analysis Population Information

Overall Number of Baseline Participants
A total of 60 participants are planned to participate in the study.

Baseline Measure Information
Patients' age, gender, eye side, additional diseases, medications used and preoperative visual acuity values will be recorded at the beginning of the study.

Baseline Measure Title
The change in the visual acuity and the change in the number of endothelial cells will be the primary outcome of the study.

Study-Specific Measure * § *(Select as many as needed)*

- Age *(Select at least one of the following):*
  - Age, Continuous: For example - mean or median age
- Sex/Gender *(Select at least one of the following):*
  - Sex: Female, Male
- Race and Ethnicity
  - Race and Ethnicity Not Collected

Measure Type *
Definition: The type of data for the baseline measure. Select one.

- Count of Participants

Measure of Dispersion *
Select one.

- Not Applicable (only if Measure Type is "Number", "Count of Participants", or "Count of Units")

Baseline Measure Data *
When the investigation is completed, information about each baseline measures data will be updated.

Unit of Measure *
Participants, mmHg, micron, millimeter

▼ 3. Outcome Measures

A table of data for each primary and secondary outcome measure by arm (that is, initial assignment of participants to arms or groups) or comparison group (that is,

analysis groups), including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any.

Note: Outcome measure information from the Protocol Section of the record will be copied into the Results Section the first time results are created.

Primary Outcome Measure:

1.Visual Acuity (Snellen)

Change from baseline

[Time Frame: Baseline and after surgery 1, 3, 6, and 12 months]

2.Endothelial Cell density (cells/mm^2)

After surgery measurements

[Time Frame: after surgery 1, 3, 6, and 12 months]

Secondary Outcome Measures:

1. Maximum (steepest) and minimum (flattest) keratometry values in the central corneal zone (K values)

Change from baseline

[Time Frame: Baseline and after surgery 1, 3, 6, and 12 months]

2. Anterior chamber depth (mm)

Change from baseline

[Time Frame: Baseline and after surgery 1, 3, 6, and 12 months]

3. Axial Length (mm)

Change from baseline

[Time Frame: Baseline and after surgery 1, 3, 6, and 12 months]

4. Central pachymetry (micron)

Change from baseline

[Time Frame: Baseline and after surgery 1, 3, 6, and 12 months]

5. Intraocular pressure (mmHg)

Change from baseline

[Time Frame: Baseline and after surgery 1, 3, 6, and 12 months]

Other Pre-specified Outcome Measures:

6. Surgical complications

Complications occurring during the surgery will be recorded.

[Time Frame: During surgery]

Groups/Cohorts	Interventions
Cohort All patients	Procedure/Surgery: Descemet membrane endothelial keratoplasty (DMEK) All participants underwent DMEK surgery

Analysis Population Information

Overall Number of Participants Analyzed
In total, we expect 60 participants to participate in the study.

Type of Units Analyzed
The analysis will be based on participants

Outcome Measure Data Table
Measure Type

- Count of Participants

Measure of Dispersion/Precision

- 95% Confidence Interval

Statistical Analyses
The required sample size was determined by power analysis based on previous studies. [G * Power, Version: 3.1.9.2 Statistical Packages]. Variance analysis (ANOVA) will be used in the statistical analysis of preoperative and postoperative 1st and 6th months, if the measurements show normal distribution in the repeated measurements. Post-hoc Bonferroni test will be used to find out whether there is a difference between the measurements. Friedman test will be used in the statistical analysis of measurements that do not show normal distribution. Wilcoxon test will be used to find out whether there is a difference between the measurements. Pearson and Spearman correlation test will be used in the correlation analysis. For statistical significance $p < 0.05$ will be accepted.

▼ 4. Adverse Event Information

Information for completing three tables summarizing adverse events.

1. All-Cause Mortality: Mortality is not expected in our study.
2. Serious Adverse Events: Serious adverse event is not expected in our study
3. Other (Not Including Serious) Adverse Events: No adverse effects due to study are expected. If any adverse event will be seen, it will be reported.

Time Frame
Adverse event data will be collected between 1 June 2019, and 1 June 2021.

Adverse Event Reporting Description [*]
Patients will be invited to examinations at regular intervals and will contact the researchers at the contact numbers provided if they see any unexpected effects.

Collection Approach for Table Default

- Systematic Assessment: Baseline and after surgery 1, 3, 6, and 12 months

Arm/Group Information
There is only a study group.

Arm/Group Title
All patients

Arm/Group Description
All participants underwent (Descemet membrane endothelial keratoplasty) DMEK surgery

Total Number Affected by All-Cause Mortality
0

Total Number at Risk for All-Cause Mortality

0

Total Number Affected by Any Serious Adverse Event
0

Total Number at Risk for Serious Adverse Events

0

Frequency Threshold for Reporting Other (Not Including Serious) Adverse Events
5

Total Number Affected by Any Other (Not Including Serious) Adverse Event Above the Frequency Threshold
0

Total Number at Risk for Other (Not Including Serious) Adverse Events
0

Adverse Event Term
A significant unexpected effect that affects the course of the study.

Organ System

- Eye Disorders

Collection Approach

- Systematic Assessment: Baseline and after surgery 1, 3, 6, and 12 months

Number of Participants Affected
0

Number of Participants at Risk
0

▼ 5. Limitations and Caveats

Overall Limitations and Caveats
In our study, only Descemet membrane endothelial keratoplasty (DMEK) surgeries were included. However, Descemet's stripping automated endothelial keratoplasty (DSAEK) surgeries were not included, and no comparative study was performed.

▼ 6. Certain Agreements

Information indicating whether there exists an agreement between the sponsor or its agent and the principal investigators (unless the sponsor is an employer of the principal investigators) that restricts in any manner the ability of the principal investigators (PIs), after the completion of the study, to discuss the results of the study at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the study. This does not include an agreement solely to comply with applicable provisions of law protecting the privacy of participants.

Are all PIs Employees of Sponsor?
Definition: Indicate whether the principal investigator is an employee of the sponsor.

- Yes

PI Disclosure Restriction Type

There are no varying agreements.

▼ 7. Results Point of Contact

Point of contact for scientific information about the clinical study results information.

Document Date: May 24, 2019

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