

**Intraocular pressure and ocular biometrics changes after phacoemulsification in  
glaucomatous patients and age matched controls, comparative study**

**September 14th, 2019**

**ICF template**

# **Informed Consent Form**

## **Researchers:**

Professor Dr. Karim Adly Raafat, Cairo University

Assistant Professor, Dr. Reham Samy Hanafy Mahmoud Allam, Cairo University

Dr. Mai Nasser Abd ElMohsen, Cairo University.

## **The purpose of the study:**

Evaluation of the effect of phacoemulsification on intraocular pressure and ocular biomechanics in open-angle glaucoma eyes compared to angle closure glaucoma eyes.

## **Procedures / actions required from the participant:**

- The participant suffering from cataract is candidate for phacoemulsification and intraocular lens implantation.
- Attendance at the date of the examination, in addition to attendance, according to the periodic follow-up of intraocular pressure (IOP), according to his medical condition. IOP and the depth of the anterior chamber and angle opening distance before and after the operation, are compared to find out the effect of phacoemulsification on these measurements.

## **The time required for patient participation:**

One month required for each patient separately (Attending the surgery requires a day to complete the entry procedures. Preparing the medical preparation and surgical supplies).

## **Risks:**

Possible risks occurring are the potential risks of cataract operations, according to global studies (intra-ocular infections, intra-ocular hemorrhages, retinal detachment, lens drop and laceration of its capsule).

## **Benefits for the participant and the community:**

The participant gets better vision and better control of IOP, and this is reflected on the community if the results are proven and the statistical significance is correct, as it reduces the need for other surgeries to reduce IOP, especially with eyes with a narrow angle in particular.

## **Protect participant privacy and data confidentiality:**

Data is collected and recorded without revealing the patient's personality or any data or images that may lead to this, directly or indirectly

## **Voluntary participation:**

The patient's participation is voluntary and he is allowed to withdraw at any time without any prejudice to his right in examination or treatment.

## **Costs of patient participation in the research:**

The participant does not bear any costs related to the research

## **Compensation:**

There is no offered compensation.

## **Withdrawal right:**

Version ...., Date .....

The participant has complete freedom to participate or withdraw without affecting the service provided to the participant.

**Alternatives available to the patient in the event of unwillingness to participate:**

The medical condition of the participant is discussed without prejudice to his right to examination or treatment.

**(Signing this consent form does not prohibit you from any of your legal rights in any way, nor does the researchers, sponsor or participating institution exempt them from their professional or legal responsibilities)**

To find out more about this study, you can contact Dr. Reham Sami Hanafi Mahmoud Allam Tel: - 00201001873843

Or call Dr. Mai Nasser Abd ElMohsen Tel: 00201020726736

In the event of health problems as a result of participating in the study, you can contact Dr. Reham Sami Hanafi Mahmoud Allam Tel: -00201001873843

Or call Dr. Mai Nasser Abd ElMohsen Tel: 00201020726736

• Or go to the outpatient clinic - ophthalmology – Kasr Alaini until one o'clock in the afternoon and the participant is given a follow-up card in advance to facilitate communication with those in charge of the research.

• In the event of a complaint, please contact the Office of the Research Ethics Review Committee, telephone number 00201003657120

If you agree to participate in this study, indicate in the appropriate place in the following part:

      : All the information in this agreement has been explained.

      : I have read and understand the information in this agreement.

Participant's Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Witness of the approval process: \_\_\_\_\_ Signature: \_\_\_\_\_

Signature of the Responsible of the Study: \_\_\_\_\_

Date: \_\_\_\_\_

Only applicable if the Research Ethics Review Committee approved it.

Valid from: / / 20 to / / 20

Receive a copy for the participant and keep the original copy with the researcher in the participant's file