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AS MODIFIED
May 17, 2021

DECLARATION OF CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY AND AUTHORIZATION TO RELEASE HEALTH INFORMATION TO PROSPECTIVE ENROLLED PATIENTS

TITLE: A PROSPECTIVE MULTICENTER STUDY TO ASSESS THE CLINICAL OUTCOMES OF LOW ENERGY LENS FRAGMENTATION CATARACT EXTRACTION IN PATIENTS UNDERGOING CATARACT SURGERY

PROTOCOL NO.: MICOR-304-101
ASPIRE® Protocol #20202832

SPONSOR: Carl Zeiss Meditec Cataract Technologies Inc.

INVESTIGATOR: Name
Address
City, State Zip
Country

STUDY RELATED PHONE NUMBER(S):

This consent form may have words that you do not understand. Ask the investigator or study staff to explain anything you don't understand. Reading this form and talking with the investigator or study staff can help you decide if you want to participate in the study. You can take a copy of this consent form home with you to show your family or friends before signing. If you decide to participate in this study, you must sign your name at the end of this form. No study tests can be done until you sign this form.

INTRODUCTION

You have been asked to voluntarily participate in this research study because you have a cataract. The study is carried out to obtain information and evaluate the clinical results of the different cataract surgical techniques. This study does not involve experimental techniques or devices that are not approved by the FDA (Food and Drug Administration).

The study sponsor, Zeiss CTI, pays the investigator for their contribution to the study.

BACKGROUND

You are participating in the study because you have a cataract and need to undergo standard cataract surgery to remove it and replace the diseased lens with an intraocular

lens implant. The surgeon will perform standard cataract surgery and will use various lens fragmentation techniques to remove the cataract. This study will collect data on the surgical results of the different lens fragmentation techniques to compare their results.

This document describes your rights as a research subject, as well as the purpose, procedures, risks, discomforts, precautions, alternative procedures, and potential benefits of the study. It is important that you understand that there are no guarantees or assurances about study-related results. Before you agree to participate in this study, it is important that you read (or have it read to you) and understand the information contained in this informed consent document.

OBJECTIVE OF THIS STUDY
The objective of this study is to gather data on the surgical results of the different surgical techniques and to compare their results.

STUDY DESIGN AND PROCEDURES
A maximum of 300 participants will be enrolled in this study. This study is expected to be conducted in a maximum of 10 study centers around the world.

Only those patients who meet the entry requirements will be eligible to participate.

Participation in this study can last up to 3 months. Your preoperative examination can occur 0-60 days prior to surgery and the study follow-up visits will last 1 month. You will need to visit the clinic for evaluations at all 5 study visits (1 visit before surgery; 1 visit for surgery; then 1 day, 1 week, and 1 month after surgery).

When you have received satisfactory answers to your questions, you will be asked to sign this consent form. After you have signed this form, you will be examined to determine if you are eligible to participate in this study. No study tests can be done until you sign this form. Your participation in the study begins the day you sign this form and enroll in the study. Your participation is completely voluntary, and you can withdraw your consent at any time. The following information pertains to planned study visits:

Exam prior to surgery
Several tests will be done that are part of a regular eye exam. Most of these tests would probably be done in preparation for cataract surgery, even if you will not be in this study. If your medical records are available, the investigator will review them. These medical records will be integrated into the study records. The pre-surgery exam includes:

• Ocular history. You will be asked questions about the eye diseases you have had and the eye treatments you have received in the past.

• Eye exam. You will have a complete eye exam, including:

1) Vision Check: You will have tests to determine how good your vision is.
2) Eye pressure check: Your eye pressure will be measured.
3) Examination of the inside of the front of the eye (the anterior chamber): The inside of the front of the eye will be checked with a microscope and a mirrored lens.

• Images of the eye: Photographs of the eye may be taken.

Initial examination
Again, your eye and vision will be retested, your eye pressure will be measured, and your eye may be photographed.

If you are still eligible to participate in the study after this evaluation, your surgery date will be scheduled.

Surgical treatment
The study doctor may prescribe medications to use before surgery.

If you participate in this study, the doctor will evaluate the hardness of your cataract, and according to it, he will classify it in two groups, (Cohort 1 and Cohort 2). Patients with soft cataracts will go in group or Cohort 1; and patients with hard or white cataracts will go in group or Cohort 2.

The surgery to be performed will be to remove the opaque lens from one eye and replace it with a conventional intraocular lens. This surgery is the same as that performed in any patient diagnosed with cataract. It is ambulatory, and you will be able to go home that same day.

The most crucial and difficult part of cataract surgery is breaking the lens into smaller pieces so that they can be removed by a very small wound (less than 3mm). In this study the lens will be broken apart by low energy mechanical lens fragmentation.

In the mechanical rupture technique, the surgeon will use a lens pre-segmentation device, which is a sharp instrument that does not require energy to break the lens into small pieces. This method allows to avoid that the tissues of the eye suffer additional damage, it is cheaper, it is single use (the device is disposable, which reduces the risk of infections). As disadvantages it has that it can damage the lens holder if much manipulation of it is required.

The patients who have been selected for group 1 or cohort 1 will have a mild to moderate cataract grade of 1 to 2+ and participants who have been selected for group 2 or cohort 2 will have a moderate to dense cataract grade of 2+ to 3+. Both cohorts of subjects will undergo the mechanical lens rupture technique with the lens pre-segmentation device.

Follow-up visits within the context of the study

To track your progress, you must return for 3 follow-up visits according to the following schedule:

- 1 day after surgery.
- 1 week after surgery.
- 1 month after surgery.

The eye examinations that will be conducted include vision testing, eye pressure measurements, slit eye examinations, and taking photographs of the back of your eye. During examinations, the study doctor may be required to insert drops that dilate your pupils, and provide anesthesia.

Additional examinations may be necessary in the event of ailments or complications in the study eye.

It is very important that you agree to return for all follow-up exams, as the success of the study depends on the data obtained from all participants during the designated period.

During follow-up visits, many of the tests done during the pre-surgery exam will be repeated. You will be asked to report any changes or problems you may notice in the eye that was treated in the study.

Your role in the study

Taking part in a research study can cause problems in your daily life. Be aware of the time commitments and responsibilities you will accept. Your responsibilities as a study participant include:

- Provide accurate information about your medical history and current conditions.
- Notify the researcher of any problems you have during the study.
- Keep all scheduled exam appointments.
- Follow all instructions of the investigator and study staff.

Possible Risks and Discomforts Due to Participation in the Study

If you decide to participate in this study, you will have eye surgery. The risks and benefits of this procedure may have already been discussed with you and are included below.

Some effects can be mild and probably won't last long and may include:

• Mild bleeding in the eye.
• Mild eye infection.
• Mild pain inside or around the eye.
• Slight change in vision.

You may have complications that are more difficult to treat and that could cause serious problems, such as:

• Serious eye infection or inflammation.
• Bleeding inside the eye.
• Healing problems in the eye.
• Chronic pain in the eye.
• Retinal detachment (detachment at the back of the eye).
• Inflammation of the gel that fills the eyeball.
• Damage to the cornea (transparent front of the eye).
• Damage to the iris (part of the eye that has color).
• Damage to the lens capsule (transparent bag that surrounds the lens).
• Changes in eye pressure (unusually low or high).
•Double vision.
•Sight loss.
• Droopy eyelids.
• Severe inflammation.

The risks for women who are pregnant, or breastfeeding are not known. If you suspect that you have become pregnant, you should tell the investigator immediately.

There are risks related to the use of eye drops that enlarge the pupil. These risks include temporary glare and blurred vision or increased pressure in the eye. You may have an allergic reaction to these eye drops.

You should report any symptoms or problems to the study clinic staff, even if you do not believe the medical device or study procedure was the cause. If you have any questions about the device or the study, feel free to ask the study doctor.

Unknown risks
You could have side effects or discomforts that are not mentioned in this form. Some of the side effects may not be known yet. You should discuss these risks with your general practitioner (GP) to determine if he considers you to be a good candidate for this type of surgery. Also, you should tell the investigator or study staff right away if you have ailments in the study eye.

BENEFITS OF PARTICIPATION
There is no guarantee that you will receive any direct benefit from participating in the study.

However, there may be an improvement in the symptoms of the disease. In addition, other patients may benefit from any information obtained from this study.

The information gained from this research can help us understand cataract and its treatment.

COST OF TREATMENT
The MICOR-304 device, as well as specific tests and procedures related to the study that your insurance does not cover, will not incur any cost to you.

INSURANCE COVERAGE
ZEISS CTI and the study physician are insured against claims from patients sustaining a study-related injury. An insurance policy has been issued which will cover you as a participant in this study in the event you suffer an injury resulting from your participation in it.

Except in the case of an emergency, no medical treatment should be performed on the eyes without first discussing it with the study investigator. You should immediately notify the study investigator of any emergency treatment you receive.

Any injury arising as a result of your participation in this clinical study must be reported immediately to the insurer. This report can be transmitted through the study investigator.

After the duration of the study, any treatment required due to an adverse event that is definitely related to the study procedure will be covered at no additional cost to the patient. The study insurance will pay for any necessary treatment.

PAYMENT FOR PARTICIPATION IN THE STUDY
You will not receive any payment for participating in this study.

ALTERNATIVES
There are alternatives to participating in this research. You can choose to have cataract surgery without the use of the MICOR-304 device, or you can choose to have the surgery with the use of the MICOR-304 device without taking part in the research.

YOUR RIGHTS AS A PARTICIPANT IN THE STUDY
Your participation in this study is voluntary. You can refuse to participate, or you can withdraw from the study at any time without negative consequences. If you want to withdraw during the study, please contact the investigator to discuss continued treatment.

By signing this form, you are not giving up any of your legal rights.

COMPENSATION FOR INJURIES
By signing this consent form, your legal right to claim compensation for injuries related to participation in the study is NOT affected. You have the right to take legal action, if you think your injury warrants it.

ORIGIN OF FINANCING
ZEISS CTI will provide the necessary funds to carry out this research study.

NEW DISCOVERIES
New information may emerge from this study that is important to your health or could change your decision to participate in the study. If this information is available, they will communicate it to you in a timely manner. You may be asked to sign a modified consent form if changes are made to the study. This type of information will be provided to you once it is available, even after the study ends.

CONFIDENTIALITY AND OBTAINING, USE AND DELIVERY OF PERSONAL INFORMATION ABOUT YOUR HEALTH
Your identity and personal records will be kept confidential and, to the extent permitted by applicable laws and / or regulations, will not be publicly available. Confidentiality will be maintained during and after your participation in the study.

Your study records will be marked with only your initials and a study identification (ID) number. The identification number will distinguish the investigator and the order in which you entered the study.

By signing this form, you agree to the collection and use of personal information about you for the purposes of this study. This data may include your name or initials, date of birth, gender, ethnicity, eye history and health information. This information about your

health may include the results of lab tests, X-rays, physical exams, and medical records. The study data about you will be kept in a safe place.

The investigator and study staff may share information about you with the sponsor. (The term “sponsor” includes any person or company contracted by the sponsor to have access to the research information during and after the study).

When possible, you will not be directly identified by this information; instead, other indirect information (codes) will be used.

Personal information about you will be used to confirm your eligibility to participate in this study, to evaluate the results of the study for security purposes, and to comply with legal and regulatory requirements. ZEISS CTI, the representatives of ZEISS CTI the Aspire IRB, as well as the regulatory authorities, such as the FDA, will be granted direct access to their original medical records for verification of procedures and / or data from the clinical study. This will be done without violating your confidentiality, to the extent permitted by current laws and regulations. By signing the written informed consent form, you consent to such access.

The information can be delivered to the Aspire IRB and to government agencies in other countries. Information about you may also be released in other circumstances, if required by law or for your benefit, in the event of an emergency. Absolute confidentiality cannot be guaranteed as information must be shared with these parties.

The results of this research can be presented at conferences or included in publications; however, your identity will not be disclosed.

You have the right to access your information and correct it, if necessary. You can discuss this with the investigator.

You may be asked to allow the study doctor or study staff to record the procedure through a microscope for training purposes. The video will only show your eye under high magnification. You may ask the study doctor for more information about this recording. You do not have to allow the study doctor or study staff to record the procedure. You can still be in the study even if you do not want the study doctor to record the procedure.

Your consent does not have an expiration date. You can withdraw your permission to collect, use and share information about yourself at any time. To withdraw your consent, you must provide the investigator with reasonable notice. In this case, you will not be able to continue participating in the study. No new information will be collected about

you after that date; however, information about you that has already been collected will continue to be used and disclosed to other persons or entities, as described in this form.

VOLUNTARY PARTICIPATION IN THE STUDY

Your participation is voluntary. You can refuse to participate or withdraw from the study at any time, without penalties or loss of benefits to which you are otherwise entitled.

The investigator may terminate your participation in the study without your consent, if the investigator believes that discontinuing your participation is in your best interest from a medical point of view.

The sponsoring company may also terminate your participation without your consent if you do not meet the study requirements or if the sponsor decides to discontinue the study.

If you decide to withdraw from the study, the investigator will provide you with information about the potential medical events or sequelae of the decision to discontinue your participation in the clinical trial prior to its termination.

If you withdraw from the study at any time, either at your request or at the discretion of the investigator or sponsoring company, the reasons for withdrawal will be recorded. If you agree, all tasks for the final visit will be completed as soon as possible after the retreat. Patients who are withdrawn from the study due to adverse events deemed to be related to the study product will be followed until resolution of the adverse events related to the study product is determined. For safety reasons, subjects who interrupt or terminate the study early will be followed up until the planned study completion period.

After completion of the study, the sponsor will not cover the cost of additional procedures and patients will continue with the standard care provided for cataract patients.

ADDITIONAL CONSIDERATIONS

By providing your consent to study participation and undergo elective surgery, you should be aware of additional safety considerations posed by the COVID-19 pandemic. It is important that you strictly follow the preventative measures recommended by local health authorities and your study doctor to minimize the risk of COVID-19.

By providing your consent to study participation, you should be aware of additional safety concerns related to the COVID-19 pandemic:

- You should be aware that potential disruptions to the study may be necessary due to current or future pandemic-related emergency restrictions, such as possible disruption of the study as a result of COVID-19 control measures may lead to delays in scheduled follow-up visits.
- If you experience an adverse safety event (i.e., a safety complication) and you delay seeing your doctor because of COVID restrictions and/or your concerns or fears about COVID risk that could potentially lead to a dangerous situation with serious permanent visual side effects including loss of vision. Adverse outcomes typically require you to return for additional and possibly frequent follow-up office visits and examinations, thus increasing your COVID-related risks.
- If you are found to have contracted COVID-19 or feel ill with flu-like symptoms during your participation in the study, you will not likely be permitted to continue routine scheduled study follow-up, thereby increasing the risk that diagnosis and treatment of potential adverse safety outcomes could be missed or delayed.

CONTACT DETAIL:
If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact your doctor or study staff as soon as possible. You can call the doctor or the study staff at any time if you have concerns or complaints. Also, if you have questions about the study procedures, if you get hurt or ill during the study, you can contact the phone number listed on page one of this document.

This research is being overseen by Aspire Independent Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at 1-877-366-5414 (toll free) if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

STATEMENT OF CONSENT

I have received written information about the clinical study and have had enough time to read it. I have also received extensive verbal information on the nature, meaning and consequences of clinical research from the study doctor in particular, on the purpose of the study, implementation, benefits, risks and insurance coverage, including your obligations. All my questions were answered to my satisfaction in an understandable manner and I have no further questions at this time. I know that I can ask questions at any time during and after clinical research.

I voluntarily give my consent to participate in the clinical study. I know that I can withdraw my consent at any time and that the treatment I receive will not be affected after doing so.

I agree that my medical data is documented for the purpose of the study and that this data is sent in a non-personalized way to ZEISS CTI and the relevant authorities. Regarding personal data, I agree that representatives of ZEISS CTI, the independent ethics committee, and the relevant regulatory authorities will be granted direct access to my original medical records.

Finally, I also give my consent for the publication of the results of the research for scientific purposes, in accordance with the data protection regulations.

If the study is carried out in several countries, I also accept that the corresponding foreign authorities see my personal data about the study.

I have received a copy of the informed consent document and know that a copy of the signed version of this consent form will be provided to me.

_____
Signature of participant

_____/_____/_____
Date (The subject must write the date personally)

_____
Participant's Name (Please Print)

DECLARATION OF THE PERSON EXPLAINING THE CONSENT

I have carefully explained to the participant the characteristics and objective of the study described above. The participant has had the opportunity to ask questions about this research study. I have been available to answer any questions the patient has about this study.

_____
Signature of person explaining consent Date

_____/_____/_____
Date

_____
Name of the person explaining the consent
(Please print)

DECLARATION BY THE INVESTIGATOR OR ASSISTANT INVESTIGATOR

I have spoken with the participant about the research study mentioned above. In my opinion, the participant understands the risks, benefits and obligations involved in participating in this research project.

_____ ___/___/___ _____
Investigator's Name Date Signature (Please Print)