Protocol Name: Vascular Changes Associated with Endophthalmitis. Pilot Study.
Protocol Code: CVAE-01
Version: 5. Version Date: October 1, 2024.
Principal Investigator: Dr. Raúl Vélez Montoya
Responsible Investigator: Dr. Benjamín Aboytes Ríos.

INFORMED CONSENT LETTER

PRESENTATION

Introduction

You are invited to participate in a clinical research study aimed at identifying the main vascular changes that may occur in the retina in patients with a history of endophthalmitis and who currently meet criteria for disease resolution.

The retina is the inner membrane of the eye, composed of several layers of cells. It receives images and transmits them to the brain through the optic nerve.

In endophthalmitis, the disease you suffer from, there is generally involvement of the vitreous and retina secondary to inflammation caused by bacteria or fungi. The purpose of this study is to increase knowledge of the changes that occur in the retinal vessels and the retina once the disease is resolved. The justification for conducting this study is that, to date, there are almost no studies demonstrating the vascular changes that occur once the disease resolves, nor the sequelae or associations with other diseases that it may have, nor a visual prognosis.

Purpose of the Study

The purpose of the study is to identify and associate changes in the retinal vessels and the retina that may occur secondary to the inflammation caused by endophthalmitis. The study is planned to include approximately 62 patients. This number was scientifically quantified.

Benefits of the Study

The study aims to advance knowledge of the vascular changes associated with endophthalmitis. There is no immediate individual benefit from participating in this protocol.

STUDY PLAN

Procedure

This is a clinical study designed to identify the changes that occur in the retinal vessels and retina following endophthalmitis.

Step-by-Step Process

1. Your general medical and ophthalmological history, which you have already provided to your attending physician, will be collected.
2. You will undergo a complete ophthalmological examination, including intraocular pressure and visual acuity measurements.
3. Fundus photographs will be taken with the Clarus 700 device.
4. A peripheral venous access will be inserted by trained nursing staff.
5. You will be administered intravenous fluorescein.
6. Several fundus photographs will be taken while the fluorescein travels through your circulatory system to visualize vascular changes using the Clarus 700 device.
7. The peripheral venous access will be removed by trained nursing staff.
8. This will be part of the ophthalmological evaluation of your condition. The remaining studies and management of your condition will be carried out as directed by your attending physician.

IMPORTANT: These procedures are in addition to the examination routinely performed during your consultation.

PROCEDURES

Initial Visit for the Study
-Signing of informed consent.
-Eligibility criteria.
-Collection of data already provided in your medical history and ophthalmological evaluation.
-Taking of photographs and performance of the tests above.

Visit one week and one month after the resolution of your condition, known as endophthalmitis.
-Complete ophthalmological examination, taking of photographs, and performance of the tests above.

Number of visits and duration of your participation: Two visits within two months.

RESPONSIBILITIES AND RIGHTS

Patient Responsibilities
Cooperate in the ophthalmologic examination with fluorescein stains. Attend your scheduled appointments.

Termination of the Subject's Participation in the Study
Your participation in the study may end for the following reasons:
● By your own choice, by withdrawing your consent. You will not be penalized or lose benefits to which you are already entitled. You are not required to explain your reasons for deciding to end the study**.**

Patient Rights
You have the right to ask any questions you may have about the study. You also have the right to withdraw from this study without any harm, penalties, or loss of benefits related to your medical care at any time. Your participation in this research study is entirely voluntary and free of charge. Your participation in the survey will incur no additional costs for you.

Risks and Inconveniences
You may experience an allergic reaction due to some component of the topical anesthetic and/or dyes and experience some discomfort, such as irritation, itching, redness, and burning in your eyes, or even the appearance of hives on your body due to an allergic reaction. Reactions occur in fewer than 1 in 10,000 procedures.

COSTS
The costs of the consultation with your attending physician, as well as any tests they request, and your treatment will be covered by you (the patient).

The additional procedures explained in this study will not generate any extra costs.

Compensation
Your participation in this study is entirely voluntary and non-profit, so you will not receive any stipend. A stipend is an amount of money paid to someone for work performed or services rendered.

Confidentiality
The results and all personal data you provided and will provide, as well as images, documents, and studies, are considered confidential. You will not be identified in any reports or publications resulting from this study. You will be determined by a number in all documents, including laboratory test results. The personal data you provide can only be reviewed by the regulatory body and the study researchers. The papers

will be stored in the Retina Department of the Association to Prevent Blindness in Mexico, located at Coyocan Hospital, Mexico City, Mexico.

CONFLICTS OF INTEREST

The study researchers have submitted a conflict-of-interest letter to the Research Ethics Committee, in which they declare that they will not receive any payment for conducting this research.

You may reconsider your decision to participate in this research project and communicate your decision. If you have any questions about the study, you should immediately contact:

Research associate
Dr. Benjamín Aboytes Ríos
Association to Prevent Blindness in Mexico, I.A.P. "Dr. Luis Sánchez Bulnes" Hospital, Vicente García Torres No. 46, Barrios San Lucas District
Coyoacán, Mexico City, Zip Code 04030.
Tel: 55 10841400, ext. 1206.

UNDERSTANDING AND CONSENT

Understanding of the Information Provided

By signing this consent form, you acknowledge that you have been informed about the questionnaires, the exceptional photographs, and the ophthalmological examination with lissamine green and fluorescein stains, as well as the inconveniences, harms, and benefits that may occur as a result of the procedure.
You certify that you have had sufficient time to read and understand the prior information. You also acknowledge that we have explained to your satisfaction all the technical language used in the description of this research study and that you have received answers to all your questions. You also confirm that you have received a duplicate copy of this informed consent form. You understand that you are free to withdraw from the study at any time, without losing any benefits or suffering any penalties.
I authorize the research ethics committee and the regulatory authority to access my medical records related to the research, understanding that it is necessary to corroborate the information provided in the reports with the source documents. Such access will always ensure my confidentiality is safeguarded. Likewise, it authorizes the use of images obtained from its studies for presentations and publications, without exposing its identity at any time.

Consent signature

((NAME OF VOLUNTEER IN BLOCK LETTERS)
"I _____ FREELY AGREE TO PARTICIPATE IN THIS STUDY"

Right thumb fingerprint
(In case you don't know how to write)

_____
Volunteer's signature

Date: ___/____/____ Time:_____:_____
dd/mmm/aaaa

_____
NAME OF THE PERSON OBTAINING CONSENT IN BLOCK LETTERS
Date:____/____/_____

_____
NAMES OF WITNESS 1
Date:____/____/_____
dd/mmm/aaaa
_____
Signature of witness 1 Time: ____:_____
Relationship with the volunteer: _____
Address:_____

_____
NAMES OF WITNESS 2
Date:____/____/_____
dd/mmm/aaaa
_____
Signature of witness 2 Time: ____:_____
Relationship with the volunteer: _____
Address:_____