Multimodal Analysis and Electroretinogram in VKH From Acute Onset – Part I

NCT03811366

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HOSPITAL DAS CLÍNICAS DA
FACULDADE DE MEDICINA DA UNIVERSIDADE DE SÃO PAULO

INFORMED CONSENT FORM

I - IDENTIFICATION DATA OF THE RESEARCH SUBJECT OR LEGAL RESPONSIBLE

1. NAME .:.....
IDENTITY Nº : ..... SEX : M Ž F Ž
DATE OF BIRTH: ...../...../.....
ADDRESS ..... Nº .....
CITY .....
POSTAL CODE:.....TELEPHONE (.....) .....

2.LEGAL RESPONSIBLE .....
IDENTITY :.....SEXO: M Ž F Ž
DATE OF BIRTH: ...../...../.....
ADDRESS ..... Nº .....
CITY .....
POSTAL CODE:.....TELEPHONE (.....) .....

II – DATA ABOUT THE RESEARCH

1. **MULTIMODAL ANALYSIS AND ELECTRORETINOGRAM IN VKH FROM ACUTE ONSET**
2. RESEARCHER: **Dra. Joyce Hisae Yamamoto Takiuti**
   FUNCTION: **Assistant Physician/Researcher**
   REGIONAL COUNCIL REGISTRATION Nº: **51804**
   HCFMUSP UNIT: **OPHTALMOLOGY CLINIC**
3. RESEARCH RISK ASSESSMENT:

NO RISK	Ž	MINIMUM RISK	**X**	MEDIUM RISK	Ž
LOW RISK	Ž	GREAT RISK	Ž		

(Probability that the individual will suffer some harm as an immediate or delayed consequence of the study)

4. RESEARCH DURATION: **2 years**

III - REGISTRATION OF EXPLANATIONS BY THE RESEARCHER TO THE PATIENT OR THEIR LEGAL REPRESENTATIVE ABOUT THE RESEARCH CONSIGNING:

1. Rationale and research objectives

You are being invited to participate in a clinical trial involving people with Vogt-Koyanagi-Harada disease. Please read this informed consent form carefully and ask any questions you may have before deciding whether to participate in the study. Your decision to consent to participate in this study is voluntary and you may withdraw from the study at any time. If you decide not to participate or to withdraw from the study, you will not lose benefits to which you would otherwise be entitled. You will be informed about any new information that may arise during the research that may change your willingness to participate in this study. Your doctor may discontinue your participation in this study, regardless of your consent, if he/she considers this to be the best course of action in your particular case.

2. Information about your disease and research objectives

Vogt-Koyanagi-Harada disease is a disease that affects structures that have melanin pigment in common. Thus, the disease affects the skin, ears, meninges and, mainly, the eye. This disease, if diagnosed early and treated properly, results

in good vision recovery. However, in some patients the inflammation does not go away easily and it remains for long periods (months) and in others the inflammation disappears completely but recurs after some time (months to years).

The cause of Vogt-Koyanagi-Harada still does not have a defined cause, but it is known that it is the result of “self-harm”. In other words, the patient's immune system, which has a primary function of defense against foreign and external organisms, attacks proteins present in the organism itself, causing the disease. In general, it occurs in people who have a genetic tendency to this "self-injury".

In this study we will perform several tests routinely used to assess the extent and activity of this disease. We will also do some laboratory tests with the material obtained from your blood sample to analyze the possible causes of this disease and why some patients have the disease in a more severe form.

If necessary, treatment to control the disease will be used and the effects on the eye and body will be monitored. Laboratory tests will be carried out with material obtained from your blood sample to control the effects of systemic medication on the body, if used.

3. Procedures that will be used and purposes, including identification of procedures that are experimental

The tests to be carried out will tell us how your visual function is. So, we will first document the changes found in your eye by taking pictures of your fundus (retinography). Autofluorescence is another type of photography using different types of light (infrared light and blue light). Changes in the vessels of the various layers of the eye will be studied using two types of dyes that will be injected into your vein. These dyes circulate through the body and the eye, and facilitate the observation of changes caused by the disease in the back of the eye (angiography with fluorescein and indocyanine). Photos will be taken for documentation and better evaluation of the fundus with contrast.

Furthermore, to document the changes in your eye fundus, we will perform a retinal tomography (optical coherence tomography). Optical coherence tomography uses invisible light to produce very detailed images of the fundus. No dye is injected and there is no contact with your eye by the device.

To assess how much these changes are harming your vision, an electrophysiological examination of the retina will also be performed (similar to the electroencephalogram examination of the “head”). These exams require a lot of your attention and last around thirty minutes each.

None of these tests are experimental and are routinely used in the evaluation of patients with “back of the eye” problems.

Blood samples will be collected with a volume of 10ml with two objectives: 1. determination of the “blood type”, if you are predisposed to this disease or not, 2. identify possible changes that medications in use may cause in your body.

4. Expected discomforts and risks

The expected risks in this study are minimal. All exams to be performed are already part of the international ophthalmological practice.

Some tests involve touching the eye with devices (ultrasound and electroretinogram) and, despite the eye being previously anesthetized, slight discomfort can be expected.

Tests using contrast (fluorescein and indocyanine angiography) can trigger mild, moderate, or, less commonly, severe side effects. The most common reaction is nausea (1-15% of cases) and eventually vomiting immediately after contrast injection. They are, in general, of short duration and the relief happens naturally or with the use of medication normally used for nausea. The most common moderate reactions are hives (allergic skin reaction with itching and redness) and fainting. There is also the remote possibility of generalized contrast allergy – about 1 in every 10,000 exams. It is important to report any allergies to medications, iodine and especially to the ingestion of seafood to the doctor responsible for your examination. These previous allergies can help predict whether you are more likely to develop this type of reaction. Severe allergies can be managed with medication. Life-threatening, however, can happen in rare cases. In case of suspected pregnancy, it is important to inform the doctor before the procedure is carried out. There may be dark pigmentation of urine and sweat in the days following the examination, without remaining this way for more than 2 or 3 days.

As for the punctures to collect your blood, there may be a slight discomfort from the puncture for peripheral venous access and removal of a small amount of peripheral blood. There may be a slight local hematoma.

In order to carry out these exams, you will need to attend on pre-scheduled dates. You must be accompanied to take photographs of the fundus of the eye due to the need for eye dilation. This dilation of the pupil leads to momentary visual difficulty, which is why we recommend that you are accompanied when you return home. In addition, we will have consultations for clinical evaluation that will be scheduled on dates that are suitable for you and the medical team. Your attendance to perform all procedures is essential for the best monitoring of your disease and the good progress of the study. Therefore, it is important that you agree and commit to attend, unless you have justifiable reasons for not attending.

The use of medications to control the disease carries a minimal risk of side effects. The prescription of these drugs will only be carried out when it is really necessary to control the eye disease. Both intravenous corticosteroid therapy to be used in the acute phase, and immunosuppressants, such as cyclosporine and azathioprine, to be used in the chronic phase, are widely accepted and used in the international medical community. None of these medications are experimental.

The main side effect described for cyclosporine is kidney toxicity, which especially affects patients over 55 years of age. Azathioprine can cause toxic effects on the liver and decrease in blood cells. The most common short-term side effects of intravenous corticosteroid therapy are potassium loss, bloating, weight gain, transient increase in blood glucose, nausea, stomach pain, acne, mood swings, insomnia, and metallic taste in the mouth. Some other side effects of corticosteroids: high blood pressure, increased lipids (fats) in the blood, osteoporosis, muscle injuries, cataracts, glaucoma, cardiac arrhythmias, thrombus formation (which can "clog" blood vessels), psychiatric symptoms (depression, insomnia and psychosis) and infections.

All these side effects will be carefully controlled by the responsible medical team through clinical and blood tests. Any eventual complications will be treated. It is important to remember that the benefit you will have with the use of a certain medication will always be considered greater than the risk of you presenting any of the side effects described, since no medication is being tested and the objective is your improvement.

5. Benefits that can be obtained

Vogt Koyanagi Harada disease is a chronic disease that can evolve slowly, in outbreaks, leading to worsening vision. The tests to be performed allow for a more accurate assessment of patients and their illness and will be performed in a standardized manner (at regular intervals). With this we want to provide you with an ideal follow-up and better treatment in order to prevent the evolution of your disease.

There is no financial compensation to study participants.

6. Alternative procedures that may be advantageous to the individual

There are several forms of treatment for Vogt Koyanagi Harada disease. However, there is no absolute standard or considered "the best". The treatment of the acute phase of the disease always uses corticosteroids, which can be administered orally (through the mouth) or intravenously (through a vein). Both present the risk of developing major or minor side effects according to the characteristics of each patient. As previously explained, the researchers believe that vein therapy can bring greater benefits to the patient and this is the form of treatment of choice for acute cases.

IV. CLARIFICATIONS GIVEN BY THE RESEARCHER ABOUT RESEARCH SUBJECT GUARANTEES CONSIGNING

1. Access, at any time, to information on procedures, risks and benefits related to the research, including to resolve any doubts.

You will be able to have access to any information and any doubts about your case and all the exams that are being carried out, through your doctor.

2. Freedom to withdraw your consent at any time and to stop participating in the study, without prejudice to the continuity of care.

Your participation in this study is completely voluntary. You will not lose health care benefits that you would otherwise have if you decide not to participate or if you withdraw from participating in the study at any time.

3. Safeguarding Confidentiality, Secrecy and Privacy.

Any information collected is strictly confidential. Your name will never be revealed in the study reports and your identity will not be communicated to third parties, and can only be provided to physicians involved in this research.

The data obtained in the research may be used for future publications, respecting their confidentiality.

4. Availability of assistance at HCFMUSP, for any damage to health resulting from the research.

Any damage to your health resulting from the research will be assisted in this Hospital at no cost. A research-related health problem is considered when it has been caused by the procedures required by the research.

V. INFORMATION ON NAMES, ADDRESSES AND TELEPHONE NUMBERS OF RESPONSIBLE PERSONS RESPONSIBLE FOR FOLLOWING THE RESEARCH, FOR CONTACT IN CASE OF CLINICAL INTERCURRENCES AND ADVERSE REACTIONS.

Dra Viviane Mayumi Sakata– Telephone: (41) 8826-3757

VI - POST-CLARIFIED CONSENT

I declare that, after being conveniently clarified by the researcher and having understood what was explained to me, I consent to participate in this Research Protocol. I also authorize the storage of samples from the collection approved by this consent form for use in future research, according to Resolution No. 347, of January 13, 2005, of the National Health Council

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São Paulo, de de 200 .

_____ Signature of the research subject or legal guardian

_____ Researcher signature