EFFECT OF METFORMIN ON ABCB1 AND AMPK GENE EXPRESSION IN ADOLESCENTS WITH ACUTE LYMPHOBLASTIC LEUKEMIA

INFORMED CONSENT

Mexico City, Mexico on_____of_____of 20_____

PARENT AND/OR GUARDIAN OF THE PATIENT:_____

PATIENT'S NAME:

SEX: (M) (F)

WITH DATE OF BIRTH: DAY_____MONTH_____YEAR_____

AGE:_____.

PATIENT NUMBER:_____

This consent is to authorize your or your child's participation in a protocol to learn whether a drug called metformin decreases the production of molecules (expression of genes called ABCB1 and AMPK) in a type of white blood cell in a sample taken from the blood of patients with acute lymphoblastic leukemia.

The treatment for leukemia is based on chemotherapy, which will be given according to the schedules for this disease administered at the General Hospital of Mexico "Dr. Eduardo Liceaga".

If you decide to accept, at the time of diagnosis, some data will be obtained from the file such as age, gender and some characteristics of the studies that will be taken. When your first bone marrow aspirate study is performed, an additional blood sample will be taken to analyze these molecules that may be present in the leukemia cells.

In this study, in addition to the conventional treatment, you may be given an extra medication called metformin. This medication will be given to you and as part of the participation in this study you agree to the administration of the medication.

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The metformin you will be given may cause abdominal pain, bloating, and in very rare cases a condition called lactic acidosis.

By agreeing to enter, the results of the evaluations that are performed to monitor the status of leukemia, such as bone marrow aspirates and blood biometry, will be obtained. The results obtained from this study will be pooled with those of the other participants and analyzed to draw conclusions.

Your participation in this protocol is voluntary and free of charge and you may decide not to participate and withdraw at any time.

In case of any discomfort or problem, you should immediately inform those responsible for the study so that the required medical attention can be provided; if this occurs, no reimbursement will be made for any expenses incurred.

This informed consent will be given to you at your first visit to the Hospital General de México Dr. Eduardo Liceaga by personnel duly trained and informed about the activities and tests performed in this unit. You understand that you may generate questions and that they will be answered to your satisfaction.

By agreeing to participate in this study you will not receive any financial compensation and failure to authorize participation in the study or to withdraw from the study will in no way detract from the quality of care the child receives at this or any other institution.

This document is drawn up in duplicate and you receive a copy for your person.

In case of doubts or clarifications regarding the project, you can contact the researchers 24 hours a day.

Principal Investigator:
Dr. Daniel Ortiz Morales, Associate Physician of the Pediatric Hemato-oncology Area. Phone: 27892000 ext. 2037. Pediatrics Service, Hospital General de México.

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To learn about the patient's rights in the research project, please contact Dr. Antonia Cervantes Barrios, President of the Research Ethics Committee, at 2789200 ext. 1164.

Signature of Responsible Physician

Name, signature, address and telephone number of parent or guardian

_____

Mother's or guardian's name, signature, address and telephone number

_____

Name and signature, address and telephone number of Witness 1

_____

Name and signature, address and telephone number of Witness 2

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