



## INFORMED CONSENT

### **Study title: Association of serum levels of 25 Hydroxy-Vitamin D with autoimmunity in pediatric patients with Type 2 Diabetes Mellitus**

Your son or daughter has been considered to carry out a research study in which the presence of factors that predispose to the development of type 2 diabetes mellitus in children and a more aggressive behavior of the disease is sought.

It is known that there are risk factors for the development of type 2 diabetes mellitus and both you and your family have one or more of these, such as: being Mexican, first or second degree relatives with the disease, being overweight or obese, data of insulin resistance, physical inactivity, diabetes during pregnancy, children weighing more than 4kg at birth, high blood pressure and dyslipidemia (alterations in blood fats), among others.

In the study we require that your child attend the Federico Gómez Children's Hospital of Mexico twice, to carry out a series of studies, which we explain below:

visit 1

a. You and your child must go to the Diabetes Clinic of the Children's Hospital of Mexico Federico Gómez on the day of the appointment, fasting for at least 12 hours (you must have dinner the day before at 7:00 p.m., afterwards only you can drink plain water).

b. On the day of the appointment, a blood sample will be obtained from your forearm with a total volume of 22 mL for the determination of laboratory tests.

c. After taking the samples, he will be evaluated by a pediatric endocrinologist who will take a clinical history consisting of an interrogation about his medical history and a complete physical examination.

d. You will be asked to answer some questionnaires about eating habits and Vitamin D intake.

visit 2

a. At this appointment, you will be given a written summary of the evaluation carried out, as well as the laboratory results (glucose, lipid profile, uric acid, insulin, C-peptide, transaminases). Likewise, you will receive indications or recommendations if necessary to improve the levels of Vitamin D in your body.

The risks of this study arise from the need to obtain blood samples. Venipunctures can cause pain and possibly bruising. The extraction of blood samples can cause slight dizziness that can be remedied by lowering the head and raising the legs.

There may be several benefits to your child from participating in this study. The identification of any alteration in the levels of Vitamin D, blood fats and blood pressure, among others, will allow us to assess the start of treatment to control and prevent these alterations from continuing to evolve. You and your child will not receive any monetary compensation for participating in this study.

During the study, the doctor in charge of the study will answer any questions you or your child have about the procedure, the risks and benefits, and the results of the study. Your participation in the study is completely voluntary and once you have accepted your participation, it can be canceled at any time without affecting the care of you or your family at the Children's Hospital of Mexico Federico Gómez

We hereby voluntarily agree for our child to participate in the research study. We have carefully read this document and understand all that it implies. In addition, we have been assured that the blood samples taken will be used only for the purposes proposed in this investigation and that the results will be notified to us and will be totally confidential. In the event that the patient and/or the guardian do not know how to write, the fingerprint will be placed.

WE ACCEPT: \_\_\_\_\_ YES \_\_\_\_\_ NO

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Father's name and signature

Mother's name and signature

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Name and signature of witness

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Name and signature of witness 2

Address \_\_\_\_\_

Address \_\_\_\_\_

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Investigator name and signature Date: \_\_\_\_\_

Responsible

Dr. Mario Molina Diaz

Children's Hospital of Mexico Federico Gómez

Dr. Márquez # 162. Col. Doctores. CP 06720. Mexico City.

Telephone: (55) 52 28 99 17 Ext. 2167



## INFORMED ASSENT

### **Study title: Association of serum levels of 25 Hydroxy-Vitamin D with autoimmunity in pediatric patients with Type 2 Diabetes Mellitus**

We are conducting a research study in children with type 2 diabetes mellitus. Doing research studies is one way to learn more about diseases. We are inviting you to participate in this project to evaluate the current condition of your disease, the risk you have of presenting other complications of the disease will be assessed.

If you decide to participate in the study, you will need to attend to have fasting blood samples taken at your first appointment. A blood sample will be taken from your arm. You will also be evaluated by a doctor so that you can answer some questions about your health history. Your doctor will perform a physical exam and measure your weight, height, blood pressure, and waistline.

At the end, you will be given some questionnaires where you will answer questions about your diet and your activities.

Another day you will be summoned so that you and your parents receive the results of the tests that were carried out on you.

The risks of this study are due to the fact that blood samples need to be taken, which can be painful or cause bruising. This study will provide us with more knowledge about diabetes mellitus in children, which we can use to pass it on to other doctors and help other children to prevent them from suffering from this disease or its complications. In addition, if we find any alteration in vitamin D or in the fats in your blood, you will receive the appropriate treatment to control and prevent these alterations from continuing to evolve.

When we have finished the study we will write a report about the results and what we have learned. Your name will not appear on this report and no one will know that you participated in the study. You can ask all the questions you have at any time and you are free to participate or not as you wish. We will continue to care for you. If you decide to participate in the study, write your name and sign.

I agree to participate: Yes \_\_\_\_\_ No\_\_\_\_\_

Printed Name \_\_\_\_\_

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

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Name and signature of witness 1

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Name and signature of witness 2

Address \_\_\_\_\_

Address \_\_\_\_\_

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

Name and signature of the responsible investigator

Dr. Mario Molina Diaz.

Children's Hospital of Mexico Federico Gómez  
Dr. Márquez # 162. Col. Doctores. CP 06720. Mexico City.