

May 5<sup>th</sup>, 2023

**Effect of the consumption of beverages added with *Stevia rebaudiana* on oral pH and Dental biofilm in Adolescents**

**INFORMED CONSENT FORM: PARENT/GUARDIAN**

**INFORMED CONSENT FORM: CHILD**

**RESEARCH STUDY. Federico Gómez Children's Hospital of Mexico  
HIM 2022-049 FF**

## INFORMED CONSENT

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

RESEARCH STUDY. Federico Gómez Children's Hospital of Mexico.  
HIM 2022-049 FF.

### **Effect of the Consumption of Beverages Added with Stevia rebaudiana on oral pH and Dental biofilm in Adolescents**

#### **Introduction.**

Your son has been invited to participate in research to measure some changes caused by beverages added with steviosides. This research will be carried out at Federico Gómez Children's Hospital of Mexico. You can or cannot allow your child to participate in it, and you can withdraw it at any time you wish. With this investigation, the researchers wish to obtain information that benefit other patients with the same characteristics as your child. Please read this document carefully and ask your questions before deciding to participate.

#### **Purpose.**

Dental caries is one of the most common diseases that affect people worldwide; it has a multifactorial nature related to dietary factors. This research seeks to find changes in the oral environment and the bacterial proliferation caused by steviosides.

#### **Request.**

For this study, your child must be a regular consumer of soft drinks, don't brush your teeth during the 24 hours before the survey, don't drink or eat during the 2 hours before the test and come up with three times at "Federico Gómez" Children's Hospital of Mexico.

#### **Procedure.**

Your child will drink 355 ml of tea lemon flavor in the first appointment. At the following meetings, your child will drink 355 ml of tea lemon flavor added with 2.2 gr. of *stevioside* or tea lemon flavor added with 7.5 gr. of sucrose. During each meeting, the researcher will have biofilm samples accumulated on the child's teeth, and the child will be asked to spit at different times into a sterile test tube.

#### **Risks and discomforts.**

The participants will be asked to refrain from oral hygiene procedures for 24 hours and from eating and drinking anything except water for two hours before the test. Your child may be hungry during this time. Your child will be able to eat after the intervention, which will take approximately 2 hours. Blood samples will not be requested for this study.

#### **Benefits.**

The information obtained in this research will help us know about caries' nutritional factors and create better recommendations.

**Cost.**

No cost to the participant.

**Accessibility/Confidentiality.**

The results will be confidential. The staff will be available to answer questions regarding test results or procedures performed. The results are personal, and only you and the team will know about them.

**Problems/Questions.**

Questions about the procedure, communicate with the physicians participating. Federico Gómez Children's Hospital of Mexico. Tel. 555228991 Ext 4304 Ph.D. América Miranda Lora or MSc. Guadalupe Carolina Barajas Torres.

The child can or cannot participate in this study; or decide to withdraw from it, not losing any benefits as a patient in this hospital.

I certify that I have read and understood the explanations of this study.  
Please complete the following information and circle your answer.

Parent's Name: \_\_\_\_\_  
Agree to participate: Yes    No  
Signature: \_\_\_\_\_

Participant name: \_\_\_\_\_  
Address: \_\_\_\_\_  
Signature: \_\_\_\_\_

Witness 1 name: \_\_\_\_\_  
Witness 1 address: \_\_\_\_\_  
Witness 1 signature: \_\_\_\_\_  
Relationship with to participant: Yes    No

Witness 2 name: \_\_\_\_\_  
Witness 2 address: \_\_\_\_\_  
Witness 2 signature: \_\_\_\_\_  
Relationship with the participant: Yes    No

Responsible investigator name: \_\_\_\_\_  
Relationship with the participant Yes    No

Second investigator name: \_\_\_\_\_  
Relationship with the participant: Yes    No

Federico Gómez Children's Hospital of Mexico. Dr. Márquez 162, Col. Doctores, Alcaldía Cuauhtémoc. C.P. 06720 Ciudad de México, México. Tel 52289917.

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

## ASSENT CONSENT

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

RESEARCH STUDY. Federico Gómez Children's Hospital of Mexico.  
HIM 2022-049 FF.

**Effect of the consumption of beverages added with *Stevia rebaudiana* on oral pH and dental biofilm in adolescents.**

### **Introduction.**

You have been invited to participate in a research study at Federico Gómez Children's Hospital of Mexico.

### **Purpose.**

In this research, we want to obtain information about mechanisms in your mouth after consuming drinks added with steviosides.

### **Benefit.**

Dental caries is a common disease worldwide, including in the adolescent population. It is difficult to reduce the presence of this type of disease due to many factors like the consumption of industrialized beverages. This study will provide knowledge that can help us understand the mechanisms of different sweeteners in developing dental diseases.

### **Process.**

For this study, we will ask you to attend for three days, with one week between them. During the intervention, you will drink tea lemon flavor. In the next meetings you will drink tea lemon flavor added with 2.2 gr. of stevioside or tea lemon flavor added with 7.5 gr. of sucrose. During each appointment, you will be asked to spit several times into a test tube, and we will obtain samples of your dental biofilm.

### **Risks and discomforts.**

For this procedure, we won't use sharp instruments. You will be asked to refrain from oral hygiene procedures for 24 hours and from eating and drinking anything except water for two hours before the test.

### **Costs.**

No cost to the participant.  
No cost to your family.

### **Questions.**

Questions about the procedure, communicate with the physicians participating. Federico Gómez Children's Hospital of Mexico. Tel. 555228991 Ext 4304. Ph.D. América Miranda Lora or MSc. Guadalupe Carolina Barajas Torres.

**Assent.**

You can or cannot participate in this study; or decide to withdraw from it, not losing any benefits as a patient in this hospital.

I have read and understood the explanations of this study.

Please complete the following information or circle your answer.

Participant name: \_\_\_\_\_

Address: \_\_\_\_\_

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

Witness 1 name: \_\_\_\_\_

Witness 1 address: \_\_\_\_\_

Witness 1 signature: \_\_\_\_\_

Relationship with to participant: Yes      No

Witness 2 name: \_\_\_\_\_

Witness 2 address: \_\_\_\_\_

Witness 2 signature: \_\_\_\_\_

Relationship with the participant: Yes      No

Responsible investigator name: \_\_\_\_\_

Relationship with the participant Yes      No

Second investigator name: \_\_\_\_\_

Relationship with the participant: Yes      No

Federico Gómez Children's Hospital of Mexico. Dr. Márquez 162, Col. Doctores, Alcaldía Cuauhtémoc. C.P. 06720 Ciudad de México, México. Tel 52289917.

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