

**Effects of carbonated beverage consumption on oral pH and bacterial proliferation in adolescents: A Randomized Crossover Clinical Trial.**

**INFORMED CONSENT FORM: PARENT/GUARDIAN  
INFORMED CONSENT FORM: CHILD**

**RESEARCH STUDY. Federico Gómez Children's Hospital of Mexico.  
HIM 2017-084 SSA 1411**

**September 25, 2017**

## **INFORMED CONSENT**

RESEARCH STUDY. Federico Gómez Children's Hospital of Mexico.

Approval by Research, Biosafety and Ethics Committees September 25, 2017.

HIM 2017-084 SSA 1411.

### **Effects of carbonated beverage consumption on oral pH and bacterial proliferation in adolescents: A Randomized Crossover Clinical Trial.**

#### **Introduction.**

Your son has been invited to participate in research to measure some changes caused by drinking coke soda. 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. This research aims to obtain information that will 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 drinking cola beverages.

#### **Request.**

For this study, your child must be a regular consumer of soft drinks, don't brush your teeth during the 48 hours before the meeting, don't drink or eat during the 2 hours before the test and come up with four times at "Federico Gómez" Children's Hospital of Mexico.

#### **Procedure.**

Your child will drink 355 ml of natural water during the first appointment. At the following meetings, your child will drink 355 ml of regular coke, diet coke, or carbonated water. During each meeting, the researcher will take biofilm samples accumulated on the child's teeth, and the child will be asked to spit at different times into a sterile bottle.

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

The participants will be asked to refrain from oral hygiene procedures for 48 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.**

Problems or questions contact with Ph.D. Juan Garduño Espinosa, Research Director. Tel. 555228991 ext. 4315 or 4109. Ph.D. América Liliana Miranda Lora. Evidence-Based Medicine. Tel. 5552289917 ext. 4304.

The child can or cannot participate in this study; or decide to withdraw from it, not losing any benefit if he is already a patient of this hospital

I certify that I have read and understood the explanations of this study.

Please complete the following information or 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.

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

## ASSENT CONSENT

RESEARCH STUDY. Federico Gómez Children's Hospital of Mexico.

Approval by Research, Biosafety and Ethics Committees September 25, 2017.

HIM 2017-084 SSA 1411.

### **Effects of carbonated beverage consumption on oral pH and bacterial proliferation in adolescents: A Randomized Crossover Clinical Trial.**

#### **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 body after consuming different cola coke.

#### **Benefits.**

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 cola coke in developing dental diseases.

#### **Process.**

For this study, we will ask you to attend for four days, with one week between them. During the intervention, you will drink natural water for the first time. Next, you will drink regular coke, diet coke, or carbonated water. During each appointment, you will be asked to spit several times into a sterile bottle, and samples of your dental biofilm will be taken.

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

For this procedure, we won't use sharped instruments. You will be asked to refrain from oral hygiene procedures for 48 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.**

Problems or questions contact with Ph.D. Juan Garduño Espinosa, Research Director. Tel. 555228991 ext. 4315 or 4109. Ph.D. América Liliana Miranda Lora. Evidence-Based Medicine. Tel. 5552289917 ext. 4304.

**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.

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