NATIONAL POLITECHNIC INSTITUTE
BIOTIC PRODUCTS DEVELOPMENT CENTER

AUTONOMOUS UNIVERSITY OF BARCELONA

INFORMED CONSENT LETTER

NCT ID Not yet assigned

"Trial of acceptability, tolerability and biochemical indicators of *Hibiscus sabdariffa* L. drink in pregnant women"

APRIL 2024

National Politechnic Institute
Biotic Products Development Center
Autonomous University of Barcelona

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2024-1 CEI-CEPROBI

INTRODUCTION

At the Biotic Products Development Center (CEPROBI) of the National Polytechnic Institute (IPN) and the Autonomous University of Barcelona (UAB), as part of the thesis work for the PhD in Sciences in Biotic Products Development and the PhD in Food Technology respectively, an evaluation is being carried out of the effect of consuming a drink with hibiscus (*Hibiscus sabdariffa* L.) on blood pressure, biochemical markers in blood such as glucose, cholesterol, triglycerides and creatinine, complete blood count and general urine test.

Because hypertensive disorders affect approximately 10% of worldwide pregnancies and are the leading cause of maternal and fetal death, and drug treatment for these complications has proven safe for the mother in most cases, the potential effects on the fetus are unknown. Because of this, strategies are being sought to help control blood pressure during pregnancy by using natural products that are safe for both mother and fetus.

Several animal and human studies involving the consumption of hibiscus calyxes (*Hibiscus sabdariffa* L.) or extracts from this plant have demonstrated its effectiveness and safety in controlling blood pressure. A beverage containing this ingredient is being developed at the IPN and the UAB, and it is important to ensure that consumers like it (acceptance) and that its consumption does not cause negative gastrointestinal symptoms (tolerability).

The objective of this study is to determine the acceptability and tolerability of hibiscus drink for four weeks by pregnant women, as well as to determine the impact on blood pressure, blood biochemical markers (glucose, cholesterol, triglycerides and creatinine) and general urine test before consumption of the drink and at the end of treatment.

PROCEDURE

The participation of pregnant women who meet the following **inclusion criteria** is required:

- Pregnant women aged 18 to 35
- In their second trimester of pregnancy
- Adequate Blood pressure ≤ 140/90 mmHg

You will not be able to participate if you have any or more of the following: **exclusion criteria**:

- Multiple or high-risk pregnancy
- Having a diagnosed hypertensive disorder or having had one in previous pregnancies
- Being allergic or intolerant to hibiscus
- Having chronic non-communicable diseases such as diabetes, cardiovascular disease, cancer, or kidney failure
- Body Mass Index ≥ 30 kg/m²

This will be verified by taking a weight and height measurement and medical history, which will be administered by a physician for approximately 30 minutes. This medical history will be conducted privately in an office at the "MEDOMAI" Comprehensive Health Services Clinic located at 401 Carlos Cuaglia Street, Gualupita neighborhood, Cuernavaca, Morelos.

If you wish, having met the inclusion criteria and not presenting any exclusion criteria, you will be considered to participate in the clinical trial.

Before starting to consume the beverage, you will be informed of the date of your blood sample collection at the MEDOMAI Clinic, as well as your blood pressure measurement. You must arrive after fasting for 8 hours between 7:00 a.m. and 9:00 a.m. The blood sample will be collected using sterile materials. It will be placed in a tube without anticoagulant (red tube), and another sample will be placed in a tube with anticoagulant (purple tube), extracting a volume of 10 ml. Blood samples will be collected by trained and experienced personnel. This same procedure will be performed after the 4-week period following consumption of the beverage.

After your blood pressure is measured and your blood sample is taken, you will be given the doses of hibiscus powder, as well as instructions for preparing the drink. The clinical trial will last four weeks, during which you will consume one dose of the drink daily. A researcher will contact you via WhatsApp once a week to request information regarding its acceptability and tolerability.

POSSIBLE RISKS

The risks involved in participating in this study are minimal, mainly due to the puncture during blood draw. You may experience pain or numbness, swelling, or bruising at the site where the needle is inserted. Research staff are experienced in these procedures and will use new, sterile equipment and gloves during the procedure.

The effects of hibiscus consumption on pregnant women have not been thoroughly studied. There are some cases reporting complications with foods rich in anthocyanins (compounds also present in hibiscus). However, consumption of these bioactive compounds has been very high and in the final stages of pregnancy, which is why low doses are recommended rather than in the final stages. On the other hand, studies have shown that hibiscus consumption during pregnancy improves the treatment of anemia and the effect of the blood pressure medication nifedipine.

BENEFITS / COMPENSATION

You will not receive any financial or in-kind compensation for your participation in this study. If you agree to participate, you will be helping to expand the available information on the development of the hibiscus drink and improve its acceptance, which may have additional health benefits for women during pregnancy, allowing us to recommend its consumption as part of a regular diet.

A physician will confidentially provide you with the results of your laboratory tests in writing, free of charge, and you will receive medical and nutritional guidance if necessary. You will receive this medical guidance throughout the trial and up to 15 days after delivery, during which time participants may communicate with the researchers. If you so wish, you will be informed of the overall results of the study at the end of the study.

CONFIDENTIALITY

All information you provide will be used exclusively for this study and will be kept strictly confidential. All information will be used solely by the project researchers and will not be made available for any other purpose.

Your information will be recorded with an alphanumeric code, not your name, so you cannot be identified when the study is published. Your personal data will be treated in accordance with the Federal Law on the Protection of Personal Data Held by Private Parties. The results of this study will be published for scientific purposes, but will be presented in a manner that prevents you from being identified.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your participation is entirely voluntary, and you may withdraw from the study at any time or when your participation entails personal risk, without any repercussions.

RESEARCHER

I have explained to _____ the nature of the study and that my participation in it is solely as a researcher. I have also been informed of the purposes of the research and the risks and benefits of participating.

I have answered all questions to the best of current knowledge.
I acknowledge that I have read and understand the applicable regulations for conducting research with human subjects and that I abide by them.

RESEARCHERS

Researcher name and signature	Researcher name and signature	Researcher name and signature

PARTICIPANT

I declare that I have been fully informed about the potential risks, inconveniences, discomforts, and benefits of my participation in the study. I have read and understand the study information, and my questions have been answered to my satisfaction.
I understand that the data obtained in the study may be published or disseminated for scientific purposes and that the information collected may be used in the future for statistical purposes. Therefore, my decision to participate in the study is completely voluntary.
If I have participated in the study, I can withdraw at any time and I cannot provide the reasons for my decision if I so wish, which will be fully respected.

Cuernavaca, Morelos on _____ of _____ of 2024.

I agree to participate in the study "Acceptability and tolerability trial of *Hibiscus sabdariffa* L. drink."

YES ( ) NO ( )

Name and signature of participant _____

Witness	Witness
Address	Address
Kinship	Kinship

If you have any questions about the concepts or procedures, you can contact Name of researcher on the phone researcher's phone or by mail researcher's mail,