Title of the study	Comparative effectiveness of point-of-care glycosylated hemoglobin measurement (POC-A1c), vs. the current standard based on oral glucose tolerance test, for the early detection of Type 2 Diabetes Mellitus (T2DM) in Colombia. EDDIT-1 STUDY
Founder Organization	Sanofi
Principal Investigator	Dr. Humberto Reynales Founder Organization Address: Transv. 23 # 97-73 Piso 8 Research Center Address: Centro de Atención e Investigación Médica CAIMED S.A.S - Carrera 4 Este No 24-65 Piso 2 Chía Cundinamarca. Phone: (601) 8707070
Date of approval of the Ethics Committee	
Ethics Committee	VITA Research Ethics Committee Address: Calle 24 #3-02 Este Chía, Cundinamarca Phone: 601-5554856 – 350 3189822 Mail: comitedeeticavita@caimed.com

Dear Madam, Dear Sir,

You are invited to participate in a research study to evaluate the comparative effectiveness of two strategies for early screening of Diabetes Mellitus guy 2. This study is performed to increase the precocious detection of Type 2 diabetes mellitus in patients, which makes it necessary to explore alternative strategies for actively searching for patients with prediabetes (prediabetes status) or undiagnosed diabetes.

This study will include a total of 902 participants over the age of 18 and under the age of 75 and will last approximately 4 months for each participant. Invitations will be sent to those who submit a result in the FINDRISC (questionnaire that determines the risk of type 2 diabetes mellitus), with a moderate risk (12-14 points), high risk (15-20 points) or very high risk (more than 20 points) of suffering the disease in the last 10 years. They will be randomly assigned in two possible groups, the first (Group A) corresponds to a glycosylated hemoglobin measurement of the day of the attention (Blood sample) and in the second (Group B) who will not receive such sample.

Introduction

Diabetes is a condition that results from a lack of the insulin hormone in a person's blood, or when the body has a problem using the insulin it produces (i.e., insulin resistance). When insulin does not work as it should, the glucose (i.e., sugar) in the blood cannot enter the body parts that need it causing sugar deficits in some parts of the body and accumulation of sugar in others. In its initial phases diabetes does not produce many symptoms. In addition, strategies are required to find people who have this disease early so that they can be offered timely treatment to avoid complications.

Purpose of the study

In this study, adults without a known diagnosis of diabetes, but with a moderate, high, or very high risk of presenting the disease at 10 years (identified by the previous application of the FINDRISC questionnaire with a score ≥12) will be invited with the aim of determining the difference in the number of patients who attend the performance of a confirmatory oral glucose tolerance test after the isolated application of the screening at the completion of the questionnaire supplemented by the glycosylated hemoglobin test, thus preventing complications or serious long-term outcomes. Before you decide to participate, you must know the possible risks and benefits, as well as the procedures of this study to make an informed decision.

This study states that to significantly increase the early detection of patients with type 2 diabetes, it is necessary to explore alternatives for active searching for patients with prediabetes or undiagnosed diabetes within the general population. These alternatives may include conducting a screening questionnaire and an out-of-office blood test as each person is currently required to attend the doctor and a laboratory to take blood samples.

Description of the study

This is an open-label, randomized, controlled study. This means that each person and research staff know the intervention they receive, this intervention is randomly assigned and will be compared against another intervention. It is expected to include 902 patients who will have one or two laboratory tests as follows: 510 patients will be given a glycosylated hemoglobin test (POC-A1c), additionally they will be given an order to take a OGTT and 392 patients will only be given that order to perform a OGTT, randomly which can be performed in the CAIMED allied laboratory or in the laboratory of your choice.

Study Requirements

- Sign and date the informed consent form.
    - Understand, accept, and sign informed consent.
- Be older than 18 and younger than 75.
- Not being pregnant or breastfeeding (referred by the participant).
- Have no known diagnosis of diabetes.
- No diagnosis or history of familial hyperlipidemia
- No regular use of corticosteroids Systemic.
- No Haemophilia or other coagulation disorders.
- Have no known history of 6 glucose phosphate dehydrogenase deficiency.
- Have no background of cancer.
- Have no known diagnosis or history of HIV.
- Have no concomitant therapy with erythropoietin in the past 6 months
- Have no known diagnosis or history of stage IV or V chronic kidney disease
- No history of transfusions prior to 3 months

Study activities

They will be randomly assigned into one of the two groups; in one group a blood sample will be taken from the tip of the finger and in the other not. Subsequently, all participants will be given an order for a blood test in the allied laboratory CAIMED or in the laboratory of your choice (Oral Glucose Tolerance Test - OGTT). This test is aimed at identifying patients with type 2 diabetes and requires a fasting period, as well as taking a standard mixture of sugar diluted in water (OGTT). Additionally, you must attend the center only on the first day of the start of the study and then follow-up calls will be made by telephone: 30 days after the delivery of the test order and if it has not yet been done in this first window of time, again a call 90 days after the inclusion in the study. If you present an impaired result, a last follow-up call will be made 30 days after reporting it to the research center to check if you started medical management.

Possible benefits of the study

You may not receive any benefits; however, your participation can help establish the best way to diagnose this disease early in the general population.

Risks of the study

This study is considered a minimal risk study, which means that the risks may be given by common procedures of everyday clinical practice. Among the risks associated with the study activities are: pain, dizziness, bruising and rarely infection at the sample site. Additionally, there are unforeseen risks.

Responsibilities of the subject

It is the responsibility of the participant to provide truthful and reliable information. Take the relevant phone calls. In addition to providing data from your medical history.

Alternatives to participation in this study

It is not the goal of this study to deliver or institute additional treatment to the one you should receive. If throughout the study you are identified as a patient who is at risk for diabetes or who has type 2 diabetes, the research staff will tell you how you should access the usual treatment for your condition by your insurer.

Confidentiality and authorization of data processing

Your data will be treated confidentially and your identity in this study will be protected in compliance with Colombian regulations of Habeas Data according to the Law 1581 of the October 17, 2012 and Decree 1377 of June 27, 2014 and the regulations that modify or replace them.

The data of his participation remain strictly confidential in the center of research. Nevertheless, you authorize that these are examined by all persons related to the research project and/or who are named by Sanofi including the study monitoring team, auditors, ethics committees, and representatives of the Health Authorities in Colombia (INVIMA) or the US Food and Drugs Administration (FDA) or any regulatory agency for inspection purposes.

The only one who will be able to access personal data that allows you to be identified (e.g., your name and ID will be the staff of the study medical team, who in turn, will be the owner of the database linked to your name and ID. You have been informed of your right to know, rectify, include, update, and request the suppression of your personal information at any moment and without any damage, as how to raise consultations o questions about your personal data which are being treated or to file complaints what will be treated in agreement to the established procedure in article 15 of Law 1581 of 2012, by which you may send a communication to the e-mail of the research physician.

Likewise, you have been informed of the right not to answer questions related to your sensitive personal data and to know the Data Processing Policy of the study doctor. You will be given a copy of this informed consent document.

Participation in the study is your decision. You are completely free to accept or refuse to participate. If you decide to participate, you can also leave the study at any time. You do not lose any rights if you do not participate, or if you participate and then decide to withdraw. Your refusal to participate will not affect your usual medical care. Once you know the study and the tests that will be carried out, you will be asked to sign this form to participate in it. If you join the study, we will collect your information, perform study procedures in case you are assigned in the glycosylated hemoglobin sample group in the care group. The study research physician may withdraw you at any time, if it is justified that this decision is in your best interest or if you do not meet the conditions to participate in the study.

You will not be paid for your participation in this research study. There will be no additional costs to you for your participation in this study. Sanofi is providing financial support for this study.

Contact Information
If you have any questions regarding the availability of medical care related to research, you can contact:

- Main researcher: Humberto Reynales Londoño
- Address: Calle 24 N°3-02 este Chía, Cundinamarca.
  Phone:(601) 8707070

If you would like to receive further information regarding your rights as a participant in this study, or discuss possible injuries as a result of this study, you may contact the chair of the independent research ethics committee.

- President of the VITA Ethics Committee - Giovanny Hernán Rincón Oyuela
- Committee of Ethics in Research VITA
- Address: Calle 24 #3-02 Este Chía, Cundinamarca
- Phone: 601-5554856 – 350 3189822
- Mail: comitedeeticavita@caimed.com

DATA SUBJECT OF RESEARCH	
FULL NAMES AND SURNAMES :	SIGNATURE OR FINGERPRINT:
IDENTITY DOCUMENT :	
ADDRESS:	
DATE:	
WITNESS DATA No.1	
FULL NAMES AND SURNAMES :	SIGNATURE:
IDENTITY DOCUMENT :	
ADDRESS:	
DATE:	
RELATIONSHIP WITH THE PATIENT:	

WITNESS DATA No. 2	
FULL NAMES AND SURNAMES :	SIGNATURE:
IDENTITY DOCUMENT :	
ADDRESS:	
DATE:	
RELATIONSHIP WITH THE PATIENT:	

NAME AND SURNAME OF THE PERSON CARRYING OUT THE INFORMED CONSENT PROCEDURE :
SIGNATURE:
DATE (DD/MMM/YYYY):

I, the undersigned, do hereby certify that I am fluent and competent in both, the English and Spanish languages, and that I have made the above translation from the original document in the Spanish language and the same is a true and complete translation to the best of my knowledge, ability, and belief. CAYETANO EDUARDO FORERO OROZCO, Sworn Translator and Interpreter Resolution # 502, – National University of Colombia – Bogotá, D.C. Place, and date of this translation: Bogotá, Colombia, 06-24-2022. Mobile telephone number: (57) 318 848 1431 Email: eduardoforeroo@gmail.com - Sworn Translation # 4918.

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