OFFICIAL TITLE:

THE EFFECTS OF PROBIOTICS ON METABOLIC BIOMARKERS, INFLAMMATION, AND THE ANTIOXIDANT SYSTEM IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

Date: 17.04.2018

Study Title: Effects of Probiotics on Metabolic Biomarkers, Inflammation, and Antioxidant Systems in Patients with Type 2 Diabetes Mellitus

INFORMED CONSENT FORM (FORM 17)

PLEASE READ CAREFULLY!!!

You have been invited to participate in this study. Before accepting to take part, it is essential that you understand the purpose of the study and make your decision freely after reading this information. Please read this specifically prepared information document carefully and ask for clear answers to your questions.

WHAT IS THE PURPOSE OF THE STUDY?

Type 2 diabetes mellitus is a disease characterized by hyperglycemia (high blood sugar) and is one of the leading causes of cardiovascular diseases, blindness, end-stage renal disease, and hospitalizations. Recent studies support that bacteria residing in the gut may play a significant role in the development and progression of diabetes. Changes in the environment of gut bacteria can affect blood glucose and blood lipids. An increasing number of recent studies have shown that probiotics can alter the gut bacterial environment and lower blood glucose and lipid levels. The aim of our study is to investigate the effects of probiotics, administered in addition to your current medication, on blood glucose and blood lipid levels.

WHAT ARE THE INCLUSION CRITERIA?

To be included in this study, you must be diagnosed with Type 2 Diabetes Mellitus and be between the ages of 35 and 65.

You must not have used any antibiotics, multivitamins and minerals, probiotics, or herbal products in the last 4 weeks. Additionally, you must not have any inflammatory bowel disease, kidney, liver, or blood diseases, immunodeficiency, infection, inflammatory rheumatism, history of cancer, cardiovascular system diseases, alcoholism, and you must not be pregnant or breastfeeding.

WHAT PROCEDURES WILL BE PERFORMED?

At the beginning of the study, your height, weight, and waist circumference will be measured, and a questionnaire will be used to collect data regarding your age and medical history.

Blood samples will be collected a total of 3 times: at the beginning of the study, at the end of the 8th week, and at the end of the 12th week.

- An 8 ml blood sample will be drawn into 3 separate tubes from a vein in your arm while you are in a sitting or supine position.
- An elastic bandage (tourniquet) will be applied 10-15 cm above your elbow. A sensation of pressure may be felt during this process.
- During needle insertion, you may feel nothing or experience momentary pain.
- The phlebotomist will locate the vein path using their index finger. If necessary, the vein may be made more prominent by gently tapping the area with the index and middle fingers. You may also be asked to open and close your fist a few times to enhance vein visibility.

- The area surrounding the venipuncture site will be cleaned with gauze saturated with 70% alcohol (isopropyl alcohol, ethanol) or 10% povidone-iodine, using circular motions outward from the site.
- Venipuncture and blood collection will be completed within 1 minute after the tourniquet is tied.
- Tubes will be filled until the vacuum is exhausted, then removed from the adapter. Once blood collection is complete and the needle is withdrawn, you will be required to press on the site with dry gauze or cotton for 2.5 minutes, release the tourniquet, and hold your arm upwards to prevent leakage.
- Subsequently, an adhesive bandage will be applied. If re-collection is necessary, the other arm may be used.
- The collected blood sample will be centrifuged to separate the serum, which will be stored at 2-8°C. Serum samples will be analyzed at the Ege University Faculty of Medicine, Department of Medical Biochemistry Laboratory.

At the beginning of the study, a probiotic tablet will be provided as a 12-week dose, to be taken orally once a day.

WHAT ARE MY RESPONSIBILITIES?
During the application period (12 weeks) related to the research, it is your responsibility not to use systemic antibiotics, multivitamins and minerals, probiotic or prebiotic preparations, nutraceuticals, or herbal products. However, if you are compelled to take any of these medications, you must inform the principal investigator. You are responsible for adhering to the treatment schedule, following the researcher's recommendations, and returning the medication boxes. The researcher has the authority to exclude you from the study if you do not comply with these conditions.

WHAT IS THE NUMBER OF PARTICIPANTS?
The number of volunteers to participate in the research is 80.

HOW LONG WILL MY PARTICIPATION LAST?
The foreseen duration for your participation in this research is 12 weeks.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?
The expected benefits for you in this research are the regulation of your blood glucose and blood lipid levels as a result of the probiotics administered in addition to your current treatment, and the potential reduction in the doses of the medications you use.

WHAT ARE THE POTENTIAL RISKS OF PARTICIPATING?
In this research, you will be given 1 tablet of probiotic per day in addition to the treatment you are currently using.

Probiotics: Adverse effects that may be observed regarding probiotics include intestinal gas and a feeling of discomfort in the stomach.

Blood Collection: Venous blood samples will be taken at the beginning, at week 8, and at week 12. There are no adverse effects associated with this specific application. However, risks associated with the blood drawing process include fainting, pain, and/or bruising. In rare cases, inflammation or a small blood clot may occur at the needle entry site. Necessary precautions will be taken by us against any potential problems.

Allergic Reactions: It is known that itching, urticaria (hives), skin rash, sudden swelling of the face, neck, lips, and mouth, and sudden swelling of the hands, feet, and ankles may occur in individuals with sensitivity to the substances contained in the probiotic during use.

PREGNANCY

The risks of probiotics to the unborn fetus or a breastfeeding child are unknown. Pregnant or breastfeeding women cannot participate in this study. You must ensure that you are not pregnant and intend not to become pregnant throughout the study. If you have childbearing potential, the study doctor will discuss appropriate birth control methods with you. If you suspect you have become pregnant during the study, you must inform the study doctor immediately. If you are pregnant, you will be withdrawn from the research without your permission.

WHICH DRUGS/FOODS ARE CONTRAINDICATED DURING THE RESEARCH?

Drugs/products that are contraindicated for concurrent use during the study include antibiotics, multivitamins and minerals, probiotic preparations, food supplements, and herbal products.

UNDER WHICH CONDITIONS MAY I BE EXCLUDED FROM THE RESEARCH?

Your doctor may remove you from the study without your permission due to reasons such as failure to fulfill the requirements of the applied treatment schedule, disrupting the study program, becoming pregnant, being exposed to a side effect related to the study drug, or to increase the effectiveness of the treatment, etc.

WHAT ARE THE OTHER TREATMENTS?

There is currently no other treatment or procedure applicable for the treatment of this diagnosis that is not being applied.

IN CASE OF ANY INJURY, WHO IS LIABLE AND WHAT WILL BE DONE?

In the event of an injury related to the research, the treatment for this situation will be provided by the principal investigator, and the incurred costs will be covered by the institution to which the researcher is affiliated.

WHO SHOULD I CONTACT FOR PROBLEMS ARISING DURING THE RESEARCH?

You may contact Dr. Aslı Kılavuz at +905323536570 to inform the Principal Investigator in advance if you are compelled to take non-study medication during the application period, to obtain additional information about the research, or for any problems, adverse effects, or other discomforts related to the study.

WILL EXPENSES WITHIN THE SCOPE OF THE STUDY BE COVERED?
No payment will be demanded from you or any official or private institution or organization under whose coverage you fall for any tests, physical examinations, and other research expenses to be incurred.

IS THERE AN INSTITUTION SUPPORTING THE STUDY?
The institution supporting the study is Ege University Scientific Research Projects Unit.

WILL ANY PAYMENT BE MADE DUE TO MY PARTICIPATION?
No payment will be made to you for taking part in this research.

WHAT SHOULD I DO IF I REFUSE TO PARTICIPATE OR WITHDRAW FROM THE RESEARCH?
Participation in this research is entirely voluntary. You may refuse to take part in the research or withdraw from the research at any stage; even in the case of refusal or withdrawal, your subsequent care will be guaranteed. The researcher may remove you from the research against your will but with your knowledge due to reasons such as failure to fulfill the requirements of the treatment schedule, disrupting the study program, or increasing the effectiveness of the treatment. In this case, your subsequent care will also be guaranteed. The results of the research will be used for scientific purposes; in the event of your withdrawal or removal by the researcher, medical data regarding you may also be used for scientific purposes if necessary.

WILL CONFIDENTIALITY BE MAINTAINED REGARDING PARTICIPATION INFORMATION?
All your medical and identity information will be kept confidential, and even if the research is published, your identity information will not be disclosed. However, research monitors, auditors, ethics committees, and official authorities may access your medical information when necessary. You may also access your own medical information whenever you wish.

STATEMENT OF CONSENT TO PARTICIPATE IN THE STUDY
I have read the 5-page text presenting the information required to be given to the volunteer before starting the research, and I have listened to it verbally. I asked all the questions that came to my mind to the researcher, and I have understood all the written and verbal explanations made to me in detail. Sufficient time was allowed for me to decide whether or not I wanted to participate in the study.
Under these conditions, I authorize the research conductor to review, transfer, and process my medical information, and I accept the invitation to participate in the said research with great willingness, without any coercion or pressure. I know that by signing this form, I will not lose the rights provided to me by local laws. A signed and dated copy of this form has been given to me.

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VOLUNTEER		Signature
Name & Surname		
Address		
TEL. & FAX		
Date		

FOR THOSE UNDER CUSTODY OR GUARDIANSHIP (PARENT OR GUARDIAN)		Signature
Name & Surname		
Address		
TEL. & FAX		
Date		

RESEARCHER IN THE TEAM / COMPETENT RESEARCHER		Signature
Name & Surname		
Date		

WITNESS (IF REQUIRED)		Signature
Name & Surname		
Title/Duty		
Date		