



Effects of the probiotic k11-tmax on symptoms and inflammatory markers in children with autism spectrum disorder

GOn1
PESQUISA & BIOTECNOLOGIA

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FREE AND INFORMED CONSENT TERMS (TCLE)

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Responsible for the research: Dr. SARHA ANDRADE LOBO DE QUEIROZ

Dear VOLUNTEER, this document you are reading is called the Free and Informed Consent Form (TCLE). It contains explanations about the study you are being invited to participate in. Before deciding whether you want your child to participate (of their own free will) you must read and understand all the content. At the end, if you decide to authorize participation, you will be asked to sign it and will receive a copy of this document. Before signing, ask all questions and clarify all your doubts about any and all aspects of the study that you do not understand well. The study team will answer your questions at any time (before, during and after the study).

It is imperative to clarify and ratify that participation is voluntary, which means that you can withdraw at any time, withdrawing your consent, without this causing you any harm or penalty, simply by contacting one of the responsible researchers.

This research seeks to evaluate the effects of using a probiotic mix called k11 and K11-Tmax enriched with supplements in children diagnosed with Autism Spectrum Disorder. If you decide to accept the invitation, your child will be subjected to the following procedures:

- Blood collection to perform tests on: Serum Cortisol, Prolactin, ultra-sensitive Pcr , and Insulin.
- Collection of feces to perform a Fecal Calprotectin test .
- Neuropsychological and pedagogical assessment.
- Recording images through video and photos.

The risks involved with your participation are: mild gastrointestinal discomfort and allergy in patients with hypersensitivity to the microorganisms present in the probiotic mix , which will be minimized through the following measures: in the case of gastrointestinal discomfort, observe the next 12 hours of the condition's evolution and, if the worsening and/or presence of epigastric pain is identified, the research team must be notified and a doctor must be sought immediately. In the case of allergic processes, the use of the probiotic must be stopped immediately, the research team must be informed and, if the allergic condition worsens with difficulty breathing, redness of the body and other signs, such as changes in vital signs, it should be immediately seek an emergency unit for evaluation and treatment carried out by a qualified professional.

If this study could cause any type of embarrassment, you do not need to carry it out.



You will have the following benefits when participating in the research: receive the K11 probiotic mix free of charge, whose effect is intended to bring benefits in reducing the symptoms of Autism Spectrum Disorder. Your child's participation may help to gain greater knowledge about the treatment of the disorder and, consequently, the search for improving the quality of life of children and families.

All medical information obtained will be preserved and treated as confidential, as well as your identity will be protected, except in cases of the participant's own interest in revealing it to third parties or anyone outside this document. In this case, the researchers and the organizing company cannot be held responsible, directly or indirectly, for the act, nor can the organizers and researchers be exempt from any civil and criminal liability.

The material with your personal information and medical data will be stored in a safe place, under the responsibility of Gon1 Gestora de Projetos Ltda, with the guarantee of maintaining secrecy and confidentiality, being accessed exclusively to obtain data for scientific and biostatistical publication purposes. . The results will be published in a way that does not identify the volunteers. The results of this work may be presented at meetings, congresses and/or scientific journals, however, it will show the general and specific results without identifying the participant or any information related to their privacy.

As provided for by Brazilian standards for research involving human beings, you will not receive any type of financial compensation for your participation in this study.

The right to use the image is granted to GON1 Gestora de Projetos Ltda, captured in video or photos, which may be used in full and/or in parts, with or without editing, for different purposes, for a period of 10 years.

You will keep a copy of this Term and any questions you have regarding this research, you can ask directly to the lead researcher **SARHA ANDRADE LOBO DE QUEIROZ**, doctor, with office in the city of Vitória, State of Espírito Santo, Praça Costa Pereira, 52 - Room 708 Ed. Micheline, Centro, CEP 29010-080, or with the **GON1 project management team** located at Avenida Nossa Senhora dos Navegantes, 955, room 719, Enseada do Sua, Vitória, ES, CEP 29050-335, or by phone **027 98806-9486** or **0800 616 4444**, and/or by email: adm@gon1.com.br .

Questions about research involving ethical principles may be addressed to the **UVV Research Ethics Committee** located on the 3rd floor of the INOTEC building, at Rua Comissar José Dantas de Melo, nº 21, Boa Vista, Vila Velha, ES, CEP: 29.102-770 , Tel.: (27) 3421-2063, E-mail: cep@uvv.br .

Opening hours: Monday to Thursday, 8:00 am to 11:00 am. Complaints and/or dissatisfaction related to the patient's participation in the research may be communicated in writing to the CEP/UVV Secretariat, as long as the complainants identify themselves, and their name will be kept anonymous.



FREE AND INFORMED CONSENT

I declare that I was duly informed and clarified by the researcher about the research **Effects of the probiotic k11-tmax on symptoms and inflammatory markers in children with autism spectrum disorder**, of the procedures involved in it, in a clear and accessible way, as well as the possible risks, as well as the benefits arising from my participation, use of the collected data and images.

I was assured that I can withdraw my consent at any time, without this causing me any harm and/or penalty.

I am aware that, regardless of all the care to be taken, professional experience and appropriate technique to be used, there is no guarantee or absolute security in the result, as it always involves risks and can lead to known and other unpredictable complications, but that everything will be done to prevent its appearance.

Accordingly.

Child's Name: _____

Name of person responsible: _____

CPF: _____

Signature: _____

Digital

Researchers:

Sarha Andrade Lobo de Queiroz
Lead Researcher

Raphaela Figueira Amorim
Assistant Researcher

Deivis de Oliveira Guimarães
Assistant Researcher