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SHORT CHAIN FATTY ACIDS PROFILES IN AMYOTROPHIC LATERAL SCLEROSIS: LONGITUDINAL EFFECTS OF DISEASE AND MEDITERRANEAN DIET INTERVENTION

[***IMPACT-ALS***]

Project period 13/05/2022-12/05/2024

03.09.2025

Subject information sheet/Informed consent form

Full title: **SHORT CHAIN FATTY ACIDS PROFILES IN AMYOTROPHIC LATERAL SCLEROSIS: LONGITUDINAL EFFECTS OF DISEASE AND MEDITERRANEAN DIET INTERVENTION**

Introduction

Before agreeing to participate in this study, you need to know the risks and benefits of participation so that you can make an informed decision. This decision is known as 'informed consent'.

It is important that you read the information below and ask any questions you feel are necessary to ensure that you understand what participating in this study means for you. Signing this Informed Consent Form will confirm that (1) you have received all of the information below, (2) this Subject Information Sheet and this Informed Consent have been explained to you, (3) you have been given the opportunity to discuss any questions you may have and any concerns you may have with your doctor, and (4) the answers to all your questions have been satisfactory. Before you decide, you may take home an unsigned copy of this form to consider whether you wish to participate in this study and to discuss this possibility with your family or friends.

Your participation in this study is entirely voluntary. You have the option to participate or not participate in this study. If you decide not to participate, you will not be penalised in any way and will not lose any benefits to which you would otherwise be entitled. Your decision will not affect your relationship with your current doctor or your current or future medical care. You may withdraw from the study at any time without penalty and without losing any benefits to which you would otherwise be entitled. If you withdraw from the study, the data collected up to the time of withdrawal may still be used.

What is the purpose of the study?

This study aims to conduct a clinical and paraclinical analysis of patients with amyotrophic lateral sclerosis. Amyotrophic lateral sclerosis is a degenerative disease that affects motor neurons, causing muscle paralysis and, in approximately 3 years, death from respiratory failure.

The purpose of this study is to analyse the particularities of the immune response and the intestinal microbiome in patients with amyotrophic lateral sclerosis, through the early identification of the particularity of neurodegenerative mechanisms through the products of the intestinal microbiome (short-chain fatty acids). We also aim to evaluate the effects that changing the diet will have on the products of the intestinal microbiome and on the progression of the disease, which will allow, to a certain extent, the identification of potential non-pharmacological therapeutic targets that could more easily influence the progression of this disease. Finally, we can identify an appropriate diet that could be included in the therapeutic plan for these patients.

What do I need to do?

If you agree to participate in this study, we inform you that the study will last approximately 1 year, during which time successive neurological evaluations will be performed, along with a detailed medical history of the onset and progression of the disease. Neurophysiological tests

(electromyography) and depression tests (Beck Depression Inventory) will also be performed, and the degree of disability will be assessed using the ALS-Functional Rate Revised.

At the inclusion visit (initial), visit 2 (approximately 6 months) and the final visit (approximately 12 months), serum samples will be collected (3 tubes at each visit) and stored in a freezer until the actual serological analysis.

What are the potential risks and side effects?

The only potential risk associated with your participation in this study is the possibility that the confidentiality of your data may be compromised. However, measures have been taken to prevent this from happening.

What are the possible benefits of participating in this study?

You will not receive any direct benefit from participating in this study, but your participation will help to collect information that may help others.

How will confidentiality be maintained?

The confidentiality of your recorded data will be maintained to the highest possible standard. Your personal information will always be treated in accordance with appropriate confidentiality standards and in accordance with all applicable data protection and confidentiality laws.

If the results of the study are published, your identity will remain confidential. Your identity will not be disclosed in any presentation or report related to this study.

Will I receive any compensation for participating in the study?

You will not receive any monetary compensation for participating in this study or for the use of your information. Participation in this study will not involve any additional costs on your part.

Contact details:

If you would like to discuss this Subject Information Sheet in more detail or if you have any questions about the study and your rights as a participant, please contact the study coordinator.

You will receive a copy of this information sheet and a signed consent form, which you should keep.
Thank you for taking the time to read this information.

Subject Informed Consent Form

- I confirm that I have received, read and understood the Subject Information Sheet and Informed Consent Form for this study. I have had sufficient time to review the information, consider my participation in this study, ask questions and receive satisfactory answers to those questions.
- I understand that my participation in this study is voluntary and that I am free to withdraw at any time without having to provide an explanation and without my medical care or legal rights being affected in any way.

- I voluntarily consent to participate in this study.

_____	_____	_____
NAME OF SUBJECT	*DATE*	*SIGNATURE*
_____	_____	_____
NAME OF DOCTOR	*DATE*	*SIGN*

After completion, one copy shall be given to the subject, one copy to the person obtaining consent, and the original copy shall be kept in the medical file.