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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

STUDY PROTOCOL

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

WP1 – Creation of the study design, informed consent for patients, definition of the study population and approval of the protocol

WP1	**Objectives**	**Status**
Deliverables	Establishment of the study protocol Ethics Committee approval	Completed
	Informed consent form	Completed

WP2 - Determination of the reagents/materials needed at all stages of the research and initiation of procurement procedures

WP 2	**Objectives**	**Status**
Deliverables	Establishing the reagents and materials needed for the research stages (list of necessary materials and equipment, with technical specifications) Establishing the working protocol for neurophysiological exploration	Completed
	Commencement of procurement procedures, contact with suppliers	Completed

WP3 - Inclusion of patients in the study, initial visit (T0), clinical evaluation, neurophysiological evaluation, collection of biological samples and SCFA analysis (SCFAGGYC-PROF)

WP 3	Objectives	Status

Deliverables	Identification of patients with ALS (n=44) and healthy controls (similar age and gender; n=40)	Achieved
	Explaining the objectives of the study and signing the informed consent form	Completed
	Clinical and neurophysiological assessment of each ALS patient, with completion of each patient's medical record (including ALSFRS-R)	Completed
	Collection of serum samples	Completed

WP4 - Reassessment of ALS patients after 6 months (visit T1): clinical and neurophysiological evaluation, collection of biological samples and SCFA analysis, and introduction of the diet

WP 4	**Objectives: Dissemination of research data within the grant**	**Status**
Deliverables	Clinical and neurophysiological assessment of each ALS patient and application of the dietary questionnaire	Completed
	Collection of serum samples	Completed
	Completion of the patient's medical file	Done
	Introduction of a dietary plan	Done

WP5 - Final reassessment of ALS patients (visit T2): clinical assessment, neurophysiological assessment, collection of biological samples and SCFA analysis

WP 5	Objectives	Status
Deliverables	Clinical and neurophysiological assessment of each ALS patient 6 months after introduction of the diet	Achieved
	Serum sample collection	Completed
	Completion of each patient's medical file	Completed
	Neurophysiological report	Done

WP6 - Serum analysis to identify serum SCFA levels

WP 6	Objectives: Analysis of stored plasma samples using specific analysis kits	Status
Deliverables	Plasma analysis sheets for the **SCFAGGYC-PROF** profile through the analysis of stored plasma samples Data entry into the database	Completed

WP 7 - Statistical analysis of collected data

WP 7	Objectives: Statistical analysis of clinical, paraclinical and electrophysiological data for each ALS patient compared to the control group	Status
Deliverables	Discovery of the SCFAGGYC-PROF profile in ALS patients at T0 compared to the control group; Discovery of the SCFAGGYC-PROF profile P-ALS in T0 and T1 evolution; Identification of changes in the dynamics of the SCFAGGYC-PROF profile in ALS patients comparing T0 with T2.	Achieved