

A precision nutrition approach based on lipid and microbiota profiles in football players

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Registration date 21/11/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/11/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In high-performance athletes, high physical activity produces stress at the cardiac, muscular and metabolic levels in general. At the cellular level, the ruptures caused by exercise must be repaired quickly and this depends on diverse factors, which may vary between individuals, some of which are controllable. Different studies indicate that physical activity promotes an inflammatory state and increases oxidative stress. To reverse these situations, supplements such as antioxidants, vitamins and fatty acids are increasingly used in sports practice, based on the idea that they are natural substances and they are not harmful. However, there are different aspects to be taken into account when using this type of product. A high dose may be harmful to the body, or a general recommendation may not be suitable for a given person. Therefore, the intake of these supplements should be considered according to the specific needs of the individual athlete. The use of new precision nutrition tools is making it possible to advance the personalisation and individualisation of nutritional interventions. In this sense, omics technologies such as erythrocyte membrane lipidomics, genomics of the microbiota composition, and the study of microbiota metabolites are very appropriate to assess the nutritional status of the athlete, and thus offer personalised nutritional and supplementation recommendations for each player.

The main objective of this project is to characterise the membrane lipid profile, the genomics of the gut microbiota and the metabolites associated with nutrition and the microbiota of the football players of Real Sociedad team in order to establish the relationship between nutritional and metabolic status and, at the same time, to carry out a personalised nutritional and supplementation intervention based on this. In addition, as this is a prospective study, the effect of the course of the seasons and the practice of football over time on these parameters will be analysed. A secondary objective is also to study the relationship between the lipidomic and microbiomic profile with other variables such as performance, endurance, recovery, injuries and diet.

Who can participate?

Female and male players which are playing in the Real Sociedad teams, that signed the informed consent to participate.

What does the study involve?

The study duration is three competitive football seasons 2024-2025, 2025-2026 and 2026-2027. Data collection (blood samples for biochemical parameters and LPMEM, stool samples for taxonomic profile of GM and SCFA profile on faeces, nutritional information through FFQ, performance, endurance, recovery and injury history accessible from medical staff and gut health and fatigue data using a wellness and Digestion-associated Quality of Life Questionnaire surveys) at two times during the season, beginning of the season and mid-season.

There was a personalised intervention of fatty acids supplements based on the lipid profile and gut symptoms.

What are the possible benefits and risks of participating?

There are not any risks of participating. The possible benefits are to enhance sport performance, inflammation state and gut health symptoms.

Where is the study run from?

Blood samples were collected at Policlinica Hospital (San Sebastian, Spain), stool samples and rest of the data were collected in spot facilities (Zubieta, San Sebastian, Spain). Data curation and supplementation recommendation was done in AZTI (Derio, Spain).

When is the study starting and how long is it expected to run for?

The study started at late September of 2024 and it is expected to finish at late 2027.

Who is funding the study?

The project is funded by Pileje Laboratories (Spain)

Who is the main contact?

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

AME-RS-2024-02

Study information

Scientific Title

Personalised intervention with fatty acid and probiotics supplements in football players across three competitive seasons

Study objectives

This project is based on the hypothesis that mature erythrocytes, the taxonomic profile of the gut microbiota (GM), and short-chain fatty acids (SCFA) in faeces provide key information about the metabolism of each individual and their relationship with nutritional intake and habits. Therefore, characterisation through these techniques is very useful for defining optimal nutritional recommendations from a precision nutrition approach.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 15/10/2024, Research Ethics Committee of the Gipuzkoa Healthcare Area (Begiristain Doktorea Pasealekua, Donostia-San Sebastián, 20014, Spain; +34 943 00 74 02; osid.cei@osakidetza.eus), ref: AME-RS-2024-02

Study design

Interventional non randomized study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

To determine the lipid profile of mature erythrocyte membrane (LPMEM), the composition of the GM and the profile of (SCFA)

Interventions

Pilot intervention study to determine the LPMEM , the composition of the GM, the metabolites associated with nutrition, lifestyle and dietary pattern in football players to carry out a nutritional intervention based on the results obtained.

In total 100 football players, 80 adult female and male football players (>18 years old) from the Real Sociedad team, playing in the first and second division of the Spanish league, and 20 players from the youth team (<18 years old) who will foreseeably have continuity in the team and will reach the first categories, are participating. Recruitment is carried out by the medical services of the Real

Sociedad in Zubietta, Spain. The inclusion criteria are be a player and be active in the Real Sociedad football team and players that signed the informed consent to participate.

The study is conducted over 3 seasons (2024 - 2025, 2025 - 2026 and 2026 - 2027). Those players who leave the club, will no longer participate in the study. In the same way, it is envisaged that people who join in the future will become part of the study.

On the other hand, other parameters were also studied, such as, nutritional habits, modifying a validated Food Frequency Questionnaire (FFQ) PREDIMED for the Spanish population, quality diet, physical activity data, and gut health and fatigue data using a wellness and Digestion-associated Quality of Life Questionnaire surveys. Additionally, other biochemical parameters

were measured (plasma lipid profile, liver functions, inflammation), along with, performance, endurance, recovery and injury history. This information was collected by medical and technical staff.

Nutritional intervention phases:

Beginning of the season (September): the parameters mentioned above are analysed to define the nutritional intervention for each player. The athletes started the intervention at this time.

Mid-season (January): after 4 months, the same parameters were measured again for a new cycle of intervention.

Each year the intervention process will be repeated as described in the previous two points.

Intervention Type

Supplement

Primary outcome(s)

LPMEM data, taxonomic and SCFA profiles are collected at two points during the seasons. The personalised supplementation was based on the LPMEM and reported gut symptoms.

Key secondary outcome(s)

Effects of the supplementation along with other variables on the taxonomic profile of GM and SCFA profile in faeces collected at two points during the seasons.

Completion date

30/07/2027

Eligibility

Key inclusion criteria

1. A player and active in the Real Sociedad football team
2. Signed the informed consent to participate

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

12 years

Upper age limit

40 years

Sex

All

Key exclusion criteria

1. Not being playing due to health reasons.
2. Not having signed the informed consent form.

Date of first enrolment

25/09/2024

Date of final enrolment

30/07/2026

Locations

Countries of recruitment

Spain

Study participating centre**Real Sociedad Fútbol Club**

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Study participating centre**Fundación AZTI**

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Study participating centre**Pileje SLU**

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Sponsor information

Organisation

Fundación Azti

Funder(s)

Funder type

Industry

Funder Name

Pileje Laboratories

Results and Publications

Individual participant data (IPD) sharing plan

Due to privacy concerns data will not be available since it could potentially be used to identify individual participants. As they are professional football players data such as date of birth or height is public and might be used for their identification.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes