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

Submission date 20/11/2024	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 21/11/2024	**Overall study status** Ongoing	
Last Edited 21/11/2024	**Condition category** Other	

Plain English summary of protocol

Backgroud 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Fitness/sport facility, Workplace

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 Zubieta, 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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/09/2023

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

Age group
Mixed

Lower age limit
12 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
100

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
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Sponsor type
Research organisation

Website
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Funder(s)

Funder type
Industry

Funder Name
Pileje Laboratories

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
20/12/2027

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