ISRCTN47135203 https://doi.org/10.1186/ISRCTN47135203

Nutritional study to determine the efficacy of dry blood spots, urine and faeces metabolite profiles for dietary assessment

Submission date
16/10/2024

Recruitment status
No longer recruiting

Registration date
22/10/2024

Overall study status
Ongoing

Last Edited
05/08/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nutritional research is trying to find better ways to understand what people eat. Current methods, like food frequency questionnaires, aren't very accurate. Researchers need new, easy, and affordable tools to get reliable results. Validating the use of dried blood spots (DBS) as a minimally invasive tool to monitor dietary fat intake, and analyzing metabolites in urine and faeces, we can better understand the relationship between diet and metabolism. This approach, combined with simple dietary questionnaires, will help improve our understanding of how diet influences health.

Who can participate?
Healthy volunteers (male and female), aged 18-65 years old.

What does the study involve?
Participants will provide general information such as age, sex, date of birth, weight, height, disease parameters, lifestyle, physical activity, and dietary habits through a brief online questionnaire, which takes 5-10 minutes to complete. Before collecting biological samples, participants will provide detailed food intake information and complete a short online digestive health questionnaire, which takes about 3 minutes.
Biological samples (capillary blood and urine) will be collected on 6 different days over 3 weeks. Faecal samples will be collected at home on days 1, 7, and 21.
The nutritional intervention involves no fish intake in the first week, followed by 2 weeks consuming 2 servings of canned mackerel and 1 serving of any other lean fish per week, while maintaining their usual diet. Daily food intake will be registered.

What are the possible benefits and risks of participating?
There are no risks of participating. The possible benefits are to enhance more accurate knowledge about dietary intake.

Where is the study run from?
AZTI (Spain)

When is the study starting and how long is it expected to run for?
April 2023 to December 2026

Who is funding the study?
European Union under Horizon Europe project
Basque Government (IKERTALENT Scholarship Program 2021) (Spain)

Who is the main contact?
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Contact information

Type(s)
Public, Principal Investigator

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
M10_2022_435MR1

Study information

Scientific Title
Pilot study on the impact of nutritional and lifestyle habits on the profile of fatty acids in dried blood Spots (DBS) and metabolites in urine and faeces

Study objectives
Incorporating the measurement of fatty acids in dried blood spots (DBS) and analyzing metabolites in urine and feces as minimally invasive tools will yield more precise information on an individual's nutritional status

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/10/2023, CEISH-UPV/EHU (Bizkaia Campus, Sarriera Auzoa, Leioa, 48940, Spain; +34 946012430; astrid.beascoa@ahu.eus), ref: M10_2022_435MR2_GARCÍA URTIAGA

Study design
Single-center nutritional intervention study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Workplace

Study type(s)
Other

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
Efficacy of dry blood spots, urine and faeces metabolite profiles for dietary assessment

Interventions
The participants of this study were recruited from AZTI staff in Derio (Bizkaia) from October to November 2023. In total, 24 healthy volunteers aged 18-65 years were involved in the study, with 18 completing the nutritional intervention study.

Participants will provide general information about lifestyle, physical activity, dietary habits and digestive health through a brief online questionnaire, which takes 5-10 minutes to complete.

Participants are required to maintain their usual diet for two weeks, recording daily food intakes. This was followed by a 3 weeks nutritional intervention period: one-week washout period restricting fish and shellfish. For the next two weeks, participants consumed two portions of canned mackerel and one portion of lean fish weekly, with no other dietary restrictions. Daily dietary habits were recorded during 3 weeks.

Capillary Blood and urine samples were collected at six time points in night fasting condition: baseline (T0), after one week of fish restriction (T1), one day after T1 (having consumed a portion of mackerel the night before of the sample collection time) (T2), after the first week of intervention (T3), one day after T3 T1 (as for T2, having consumed a portion of mackerel the night before of the sample collection time) (T4), and after the second week of intervention (T5). Fish and shellfish intake was restricted 24 hours before all collection points except T2 and T4.

Faeces samples were collected only at three time points (T0, T1 and T5).

Intervention Type
Other

Primary outcome measure
1. General information about lifestyle, physical activity, dietary habits, and digestive health is measured using a brief online questionnaire at baseline
2. Daily food intake is measured using daily food records during the two-week usual diet period and the three-week nutritional intervention period
3. Capillary blood samples measured at baseline (T0), after one week of fish restriction (T1), one day after T1 (T2), after the first week of intervention (T3), one day after T3 (T4), and after the second week of intervention (T5)
4. Urine samples measured at baseline (T0), after one week of fish restriction (T1), one day after T1 (T2), after the first week of intervention (T3), one day after T3 (T4), and after the second week of intervention (T5)
5. Faeces samples measured at baseline (T0), after one week of fish restriction (T1), and after the second week of intervention (T5)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
05/04/2023

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Healthy male and female aged 18-65 years old.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
20

Total final enrolment
24

Key exclusion criteria
1. Diagnosed disease.
2. Taking medication.
3. Consuming or having consumed omega-3 supplements in the last 6 months.
4. Cancer in the last 6 months.
5. Pregnant or breastfeeding women.
6. Have undergone a nutritional intervention diet in the last 6 months.

Date of first enrolment
30/10/2023

Date of final enrolment
30/11/2023

Locations

Countries of recruitment
Spain

Study participating centre

AZTI Foundation
Food and Health,
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Sponsor information

Organisation
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Sponsor type
Research organisation

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Funder(s)

Funder type
Government

Funder Name
European Union Horizon Programme

Funder Name
Basque Government (IKERTALENT Scholarship Program 2021)

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer reviewed journals. Work in progress will also be presented at CoDiet EU project group meetings and at relevant conferences.

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made publicly available. All data will be published as group summaries and anonymised.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/08/2025	05/08/2025	Yes	No