

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/10/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/08/2025	Condition category Other	<input type="checkbox"/> 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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Public, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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, Sarriena 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

Study type(s)

Other

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(s)

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)

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/12/2026

Eligibility

Key inclusion criteria

Healthy male and female aged 18-65 years old.

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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,
Parque Tecnológico de Bizkaia,
Astondo Bidea E609
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Sponsor information

Organisation

Fundación AZTI

Funder(s)

Funder type

Government

Funder Name

European Union Horizon Programme

Funder Name

Basque Government (IKERTALENT Scholarship Program 2021)

Results and Publications

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