ISRCTN13901439 https://doi.org/10.1186/ISRCTN13901439

Personalised nutrition intervention for breast cancer survivors based on individual molecular analyses (nutrigenetics, lipidomics and microbiomics)

Submission date
05/08/2021

Recruitment status
No longer recruiting

Registration date
19/10/2021

Overall study status
Completed

Last Edited
02/11/2023

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
It is well known that cancer survivors have an increased risk of suffering from other chronic diseases, such as diabetes and cardiovascular diseases, as well as increased risk of recurrence and second malignancies. In an effort to prevent, or at least reduce, the severity of many of these diseases, a healthy and balanced diet is currently promoted by numerous cancer organizations to ensure optimal health status.
A clinical nutritional trial will be carried out with 50 breast cancer survivors, to evaluate the benefit of personalized nutritional advice on their metabolic and nutritional status. Nutritional advice will be based on individual metabolic and genetic profiles determined at the beginning of the intervention, as well as from food frequency questionnaires to determine habitual dietary intake. Intestinal microbiota will be measured throughout the intervention to assess the impact of the personalized nutritional advice on gut health. Efficacy of the nutritional advice will be determined by whether individual metabolic profiles can reach an optimal metabolic state.

Who can participate?
Breast cancer survivors.

What does the study involve?
The study involves a few hospital visits in 1 year, where blood samples will be taken from participants and they will personally meet the nutritionist.

What are the possible benefits and risks of participating?
The participants will benefit from a personalised diet (intervention group) or healthy general diet (control group). There are no other risks than the ones associated with the blood extraction procedures.

Where is the study run from?
AZTI (Spain)

When is the study starting and how long is it expected to run for?
December 2020 to May 2024

Who is funding the study?
Spanish Association Against Cancer (AECC)

Who is the main contact?
Itziar Tueros PhD, itueros@azti.es

Contact information

Type(s)
Scientific

Contact name
Dr Itziar Tueros

ORCID ID
https://orcid.org/0000-0002-7609-5435

Contact details
Parque Tecnológico de Bizkaia
Astondo Bidea 609
Derio
Spain
48160
+34 667174290
itueros@azti.es

Type(s)
Public

Contact name
Dr Mercedes Caro

ORCID ID
https://orcid.org/0000-0002-9507-9502

Contact details
Parque Tecnológico de Bizkaia
Astondo Bidea 609
Derio
Spain
48160
+34 667100352
mcaro@azti.es

Additional identifiers

Protocol serial number

TUE-SUR-2018-01

Study information

Scientific Title
Precision nutrition for breast cancer survivors based on molecular tools: nutrigenetics, lipidomics and microbiomics

Acronym
SUMA

Study objectives
The understanding of the interactions among diet and metabolism is necessary to formulate the best nutritional recommendations and thus help people achieve their health goals. Consequently, through a methodology that integrates different omic tools, it is feasible to evaluate each patient individually, and based on their molecular characteristics, it is possible to design a personalized nutritional monitoring strategy considering diet and supplementation adapted to their nutritional requirements. This strategy would work as a guide for the control and care of the survivors' health, not only at the time of the check-up but also in the future

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/07/2021, Research Ethics Committee of the Health Area from Gipuzkoa (PºDoctor Beguiristains/n. 20014 Donostia-San Sebastian, Spain; +34 943007402; mjose.velazquezzubicoa@osakidetza.eus), ref: TUE-SUR-2018-01

Primary study design
Interventional

Study design
Prospective interventional randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Nutritional and metabolic status, and well being of breast cancer survivors

Interventions
Prospective randomized controlled clinical trial with nutritional intervention for a year with a total of 50 breast cancer survivors. Participants will be randomly divided into two equal size groups: control (C) and personalized diet (D).

At the beginning of the study, blood samples will be obtained for the analysis of membrane lipidomic, nutrigenetic and epigenetic and biochemical parameters. Stool samples will be also collected to analyse gut microbiome. The anthropometric parameters will be also measured, and all patients will complete a validated quality of life (QoL) questionnaire and food frequency questionnaire (FFQ).

The Diet Group (D) participants will be provided with a personalized nutritional strategy (diet + supplementation) based on the erythrocyte membrane lipid profile and genetic profile, that will last 12 months.

The control group (C) will not receive personalized nutritional advice but they will have a general recommendation based on the Mediterranean diet and a placebo supplement. Follow-up questionaries and analyses will be done at 6 and 12 months.

Randomisation:
Oxmar software will be used. Groups will be distributed according to a random assignment sequence. In this way, we increase the probability that the two groups (control and intervention) are comparable with respect to age and pre- and post-menopause. In addition, the OxMaR system allows the concealment of the randomization sequence (OSA), as required by the CONSORT directive, since an SSL security and encryption system will be used, and a password access system to keep the randomization sequence hidden.

Intervention Type
Behavioural

Primary outcome(s)
1. Metabolic status will be measured as the rebalance of the lipidomic analyses and other biochemical parameters (standard biochemistry parameters: blood cholesterol, TG.) together with anthropometric parameters at 6 and 12 months.
2. Well-being will be measured using validated questionaries (EORTC QLQ-30 or similar) at 6 and 12 months.
3. Improvements of dietary habits will be assessed by validated food frequency questionnaire (FFQ from predimed) at 6 and 12 months.

Key secondary outcome(s)
Cancer recurrence: relapses will be measured at 12 months using patient records

Completion date
30/05/2024

Eligibility

Key inclusion criteria
Breast cancer survivors (at least 6 months after treatment), with hormonal treatment

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

Total final enrolment
50

Key exclusion criteria
1. Metastasis
2. Severe malnutrition
3. Allergy to fish
4. Any difficulty to take supplements
5. Without gallbladder

Date of first enrolment
01/09/2021

Date of final enrolment
20/09/2022

Locations

Countries of recruitment
Spain

Study participating centre
Fundación Onkologikoa Fundazioa. Unidad de Gestión Clínica de Cáncer, Osakidetza
P. Dr Beguiristain 121.
Donostia- San Sebastian
Spain
20014

Sponsor information

Organisation
AZTI - Member of the Basque Research & Technology Alliance

Funder(s)

Funder type
Charity

Funder Name
Fundación Científica Asociación Española Contra el Cáncer

Alternative Name(s)

Scientific Foundation, Spanish Association Against Cancer, Fundación Científica, Fundación Científica de Asociación Española Contra el Cáncer, Fundación Científica de la Asociación Española Contra el Cáncer, Fundación Científica AECC, FCAECC

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Spain

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 available

IPD sharing plan summary
Not expected to be made available