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Personalized nutrition for cancer patients in chemotherapy treatment.

Submission date
13/05/2019

Recruitment status
No longer recruiting

Registration date
20/05/2019

Overall study status
Completed

Last Edited
20/05/2019

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims.
Cancer is one of the leading causes of morbidity and mortality in our society, being responsible for nearly one-sixth of deaths and is expected to rise by about 70% over the next two decades. In the last years, many epidemiological studies related to the assessment of the relationship between nutrition and cancer have been done. However, studies which focus on the role of nutrition for the oncological patient are less frequent. It is commonly agreed that a poor nutritional status during cancer treatment weakens the patient, renders the administration of an appropriated treatment difficult, and increases treatment side-effects. There are several guidelines providing nutritional recommendations for cancer patients during the disease, mainly addressed to minimize treatment side effects. Despite the increasing demand for specific nutritional recommendations during the disease, tools for personalized nutritional indications and nutrition support are not yet used routinely as an adjunct to treatments.

In a previous study, we found that cancer patients had an altered lipid metabolism compared to a healthy population. The objective of this study is to evaluate if personalised nutritional advice based on the measure of the lipid metabolism of each the patient can provide an improvement for the nutritional and metabolic status of the patients during the chemotherapy treatment. The lipid profile will be measured by the lipid analysis of the red blood cell membranes. Patients in the diet group will receive personalised advice for diet and fatty acid supplements. At the end of the chemotherapy (6 months), the lipid profile will be measured again, together with the quality of life and other clinical parameters to assess the effect of the personalised diet.

Who can participate?
Cancer patients who initiate a chemotherapy treatment with a life expectancy of at least 1 year, age less than 70 years and a body mass index (BMI) less than 35.

What does the study involve?
Patient participation in this study involves:
To complete a questionnaire that collects information regarding eating habits, taste and smell alterations, food preferences and quality of life, through personal interviews taking advantage of visits to the Outpatient Unit of Onkologikoa hospital. This questionnaire will be completed three times throughout the chemotherapy treatment (time 0, 3 months and 6 months)

Blood extraction for lipid analysis and biochemical parameters (2 tubes of 3 mL) twice throughout the study (time 0 and 6 months)
To follow the nutritional recommendations defined according to your individual needs

What are the possible benefits and risks of participating?
We consider that this clinical trial has low risk, new experimental drugs are not being used. We will work with nutritional supplements of fatty acids, currently available on the market, of proven quality, previously used in clinical trials and in safe doses (not exceeding those recommended by the European Food Safety Agency (EFSA)).

In addition, the nutritional recommendations that will be provided, are based on the Mediterranean diet, a balanced diet and with a scientific basis for its benefit in the prevention of chronic diseases such as cardiovascular diseases and cancer.

Likewise, this study will contribute to generate knowledge and discover new nutritional strategies for cancer patients during chemotherapy treatment.

Where is the study run from?
Onkologikoa Foundation, Located in San Sebastian, Basque Country-Spain.

When is the study starting and how long is it expected to run for?
The trial started on 26/06/2017, and it is expected to end on 04/10/2019

Who is funding the study?
This work was funded by AZTI and Onkologikoa Foundation.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1

Study information

Scientific Title
Personalized nutrition for cancer patients in chemotherapy treatment according to erythrocyte membrane lipid profile.

Acronym
CALIMA

Study objectives
This project is based on the hypothesis that mature erythrocytes are indicators of altered lipid metabolism in cancer patients and through a personalized nutritional plan (nutrition advice + supplementation) it is possible to recover the balance of the lipid profile at the cellular level of cancer patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/12/2016, the Ethics Committee of Clinical Research of the Health Area of Gipuzkoa (Pº Doctor Beguiristains. 20014. San Sebastian-Spain; ceic.eeaa@euskadi.eus; +34 945 01 92 96; +34 945 01 56 34), ref: 1090/2015.

Study design

Single centre, prospective randomised controlled clinical trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Cancer

Interventions
A prospective controlled clinical trial with intervention in the diet for six months in cancer patients from the Onkologikoa Foundation (single-centre) will be conducted. After diagnosis and prior to chemotherapy treatment, participants will be recruited and randomly assigned to two groups: diet and control. Patients will be randomized (following a table of random numbers generated by a computer) considering age, BMI and molecular characteristics of the tumor [expression of human epidermal growth factor 2 (HER2)] in a 1: 1 ratio to each of the two groups.

The lipid profile in the erythrocyte membrane will be analyzed for all participants. Data regarding dietary habits, quality of life and clinical data will be also collected. Patients in the diet group will receive personalized nutrition advice and fatty acid food supplements, based on their erythrocyte lipid profile for the next six months. Food supplements will come from Lipinutragen brand because of their already tested good quality. These supplements contain long chain fatty acids (EPA, DHA), gamma-linolenic acid and alfa-linolenic acid in doses recommended by EFSA. The diet will be based on Mediterranean diet guidelines and adjusted for different fat families. The control group will not receive any personalized advice, they will follow the general recommendations according to the Mediterranean diet.

At the end of the treatment, the lipid profile will be measured again. Both groups will be compared to evaluate the effectiveness of the nutritional treatment (personalized advice + supplementation) to recover the balance in the erythrocyte lipid profile in six months. Other biochemical parameters related to lipid metabolism and inflammation, as well as the quality of life of patients, will be also evaluated.

Intervention Type
Supplement

Primary outcome(s)
The lipid profile of the erythrocyte membrane is measured using GC-MS (Gas Chromatography Mass Spectrometry) in blood simples (1 ml) at baseline and the end of chemotherapy.

Key secondary outcome(s))
1. Quality of life is measured using validated EORTC questionnaires (QLQ-C30) and a specific module for different types of cancer (QLQ-BR23, QLQ-CR29, QLQ-OV28 and QLQ-PR25) at an intermediate point of the intervention treatment and at the end of the chemotherapy treatment.
2. Sensory alterations in taste, smell and appetite, and food preferences are measured using a questionnaire (defined in Amézaga J., et al., 2018) at baseline, at an intermediate point of the intervention treatment and at end of the chemotherapy treatment.
3. Nutritional habits are measured using a food frequency questionnaire (validated for the

Spanish population in the PREDIMED study - Fernandez-Ballart, J.D., et al., 2010) at baseline and at the end of the chemotherapy treatment.

Completion date
30/11/2019

Eligibility

Key inclusion criteria
1. Patients of any type of Cancer who initiate a chemotherapy treatment, and who understand their participation in the trial.
2. Neoadjuvant, adjuvant and metastatic treatments will be considered.
3. A life expectancy of at least 1 year.
4. Age less than 70 years.
5. A body mass index (BMI) less than 35.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Diabetic or with other risk factors related to lipid metabolism such as metabolic syndrome.
2. Allergy to fish.
3. Severe malnutrition, cachexia or anorexia.

Date of first enrolment
28/06/2017

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
Spain

Study participating centre
Onkologikoa Foundation.
P. Dr Beguiristain 121.
San Sebastian

Spain
20014

Sponsor information

Organisation
AZTI

Organisation
Onkologikoa Foundation

Organisation
Tecnalia

ROR
https://ror.org/02fv8hj62

Funder(s)

Funder type
Research organisation

Funder Name
AZTI

Funder Name
Onkologikoa Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Not expected to be made available