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Mediterranean protocol diet rich in whole grains to treat the risk factor "Metabolic Syndrome" in cancer patients

Submission date
05/10/2015

Recruitment status
No longer recruiting

Registration date
19/10/2015

Overall study status
Completed

Last Edited
08/10/2015

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
Metabolic syndrome is a term used to describe a combination of factors which increase a person' s risk of cardiovascular disease (disease of the heart and/or blood vessels). Many of these factors are linked with obesity, such as high blood pressure, cholesterol and body fat. Obesity is therefore considered to be the primary cause of metabolic syndrome, although there is evidence that it is related to insulin resistance. Insulin resistance is where levels of insulin are so high that the cells in the body stop reacting to it. This means that the body is unable to process sugars properly and so blood sugar can become very high (hyperglycaemia). Metabolic syndrome also puts people at risk of developing cancer, and so improving the factors which make up metabolic syndrome could potentially help prevent some cancers. The Mediterranean diet is considered to be one of the healthiest diets worldwide. Rich in fruit, vegetables and whole grains, it has been shown to reduce the risk of cardiovascular disease and can keep obesity under control. The aim of this study is to find out whether a Mediterranean diet that is also high in fibre can help to reduce the factors which make up metabolic syndrome in cancer patients.

Who can participate?
Adult cancer patients showing signs of having metabolic syndrome.

What does the study involve?
Participants are randomly allocated into two groups. The first group are given a diet rich in whole grains and omega 3 fatty acids for a period of six months. Throughout the study, participants are asked to keep a food diary and attend weekly meetings in order to provide support and encouragement. The second group are provided with general information about a healthy diet with the same nutritional recommendations as the first group at the start of the study. No additional sessions are offered to provide help and support throughout the study for these participants however. At the start and end of the study participants in both groups are measured to find out if they have lost weight, and undergo blood tests to check their blood fat, cholesterol and sugar levels.

What are the possible benefits and risks of participating?
Participants may benefit from resolution of their metabolic syndrome because of the change to their diet. There are no risks of participating in the study.

Where is the study run from?
National Cancer Institute "G. Pascale" (Italy)

When is the study starting and how long is it expected to run for?
May 2014 to July 2015

Who is funding the study?
National Cancer Institute "G. Pascale" Foundation (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effects of Mediterranean-style diet on inflammation markers and reversion of metabolic syndrome in cancer patients: role of plasmatic calprotectin

Acronym
OncoMedDiet

Study objectives
A Mediterranean diet with higher grain fiber intake would reduce the components of the metabolic syndrome in cancer patients independently of cancer stage or therapy, compared to a habitual Mediterranean diet.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre pilot randomised parallel trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Metabolic syndrome

Interventions
Cancer patients were randomly assigned to either the intervention or the control diet. All participants in the study did not follow any kind of diet treatment eight months before the study. In addition, all participants did not practice physical exercise and maintained a constant weight at about 12 months and before the start of the study, each patient completed a daily food diary for initial screening test.

Intervention diet: Participants were given detailed information about the expected slimming, anti inflammatory and protective effects on its lipid and glucose homeostasis consuming suggested foods. In fact, we organized weekly meetings with cancer patients in order to accurately follow the course of the diet by using food diaries, providing also detailed explanations, psychological support and motivation throughout 6 months of diet. The caloric breakdown of the diet given in the intervention group was based on the following distribution: carbohydrates 50-55%, proteins 15-20%, total fat around 30% and saturated fat less than 10%.

Control diet: Participants followed general information about healthy food choices at baseline and at subsequent visits but were offered no specific individualized program. However, the general recommendation for macro-nutrient composition of the diet was similar to that for the intervention group (carbohydrates, 50-55%, proteins 15%-20% and total fat 30%.

Intervention Type
Other

Primary outcome(s)
1. Metabolic syndrome markers (waist circumference, blood pressure, HDL-cholesterol, triglycerides, fasting blood glucose) measured using anthropometrics and blood analysis at baseline, 2, 4 and 6 months
2. Plasma calprotectin measured using blood analysis at baseline, 2, 4 and 6 months

Key secondary outcome(s))
1. C-Reactive Protein measured by blood analysis at baseline 2, 4 and 6 months
2. Homocysteine measured by blood analysis at baseline 2, 4 and 6 months
3. Insulin measured by blood analysis at baseline 2, 4 and 6 months
4. HOMA-IR measured by blood analysis at baseline 2, 4 and 6 months
5. LDL-cholesterol measured by blood analysis at baseline 2, 4 and 6 months

Completion date
14/07/2015

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. Oncology patients
3. Have at least three of the following characteristics:
3.1. Waist circumference of at least 88 cm in women and 102 cm in men
3.2. Low levels of serum high density lipoprotein cholesterol (HDL), specifically less than 40 mg /dL for men and less than 50 mg/dL for women (or taking drug treatment for reduced HDL-C)
3.3. Hypertriglyceridemia with triglycerides level of at least 150 mg/dL (or taking drug treatment for elevated triglycerides is an alternate indicator)
3.4. Systolic blood pressure of at least 130 mmHg and diastolic blood pressure of at least 85 mmHg (or taking antihypertensive drug treatment in a patient with a history of hypertension)
3.5. Fasting plasma glucose value of 100 mg/dL or greater due to loss of glucose homeostasis (or taking drug treatment of elevated glucose is an alternate indicator)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with cognitive and psychosocial problems
2. Genetic disorders
3. Smokers
4. Drug addicts or abusers of alcohol (consumption of at least ≥500 g/wk in the last year)

Date of first enrolment
10/06/2014

Date of final enrolment
13/01/2015

Locations

Countries of recruitment
Italy

Study participating centre
National Cancer Institute "G. Pascale"
Department of Cardiology
Via M. Semmola
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Study participating centre
National Cancer Institute "G. Pascale"
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Sponsor information

Organisation
National Cancer Institute "G. Pascale" Foundation

ROR
https://ror.org/04tfzc498

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Cancer Institute "G. Pascale" Foundation

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date