ISRCTN11445521 https://doi.org/10.1186/ISRCTN11445521

N-3 polyunsaturated fatty acids and obesity

Submission date	Recruitment status	[_] Prospectively registered
26/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/02/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/03/2023	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims:
The mechanisms involved in maintaining homoeostasis in the body decrease in obesity. Biomarkers might indicate the early metabolic and proinflammatory consequences of obesity. Bioactive compounds like n-3 PUFAs might prevent the decline in organ function in people who are obese. The aim in this study is to find out whether a combined intervention (diet and n-3 PUFA) alters the metabolic, inflammatory and genetic biomarkers in obese subjects.

Who can participate?
Adults who are and are not obese

What does the study involve?
After a detailed medical examination, all individuals will receive 2 weeks of an adaptation diet. Biochemical estimations (at fasting, postprandial tests, oral glucose and oral lipids tolerance tests and genetic tests) will be performed and then all subjects will be assigned to different diet groups (low calorie or isocaloric diet). Additionally, subjects will be randomly allocated to receive n-3 PUFA or placebo for 3 months. Every 2 weeks all subjects will receive intensive group and individual education about dietary habits. Medical examination and laboratory tests will be done.

What are the possible benefits and risks of participating?
The direct benefit for participants is detailed assessment of their health status—medical examination, laboratory tests and ultrasonography (if necessary). There is a very small chance of infection at the site of the insertion of the needle.

Where is the study run from?
Jagiellonian University Medical College (Poland)

When is the study starting and how long is it expected to run for?
From September 2009 to February 2015

Who is funding the study?
European Commission (Belgium)

Who is the main contact?
Professor Aldona Dembinska-Kiec
mbkiec@cyf-kr.edu.pl

Contact information

Type(s)
Scientific

Contact name
Dr Aldona Dembinska-Kiec

Contact details
Kopernika 15a
Krakow
Poland
31501
+48 12 4214006
mbkiec@cyf-kr.edu.pl

Type(s)
Scientific

Contact name
Dr Malgorzata Malczewska-Malec

ORCID ID
http://orcid.org/0000-0002-3522-0711

Contact details
Kopernika 15a
Krakow
Poland
31-501
+48 12 4214006
mbmalec@cyf-kr.edu.pl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Caloric restriction and postprandial stress markers in healthy and obese people taking n-3 polyunsaturated fatty acids: BIOmarkers of Robustness of Metabolic Homeostasis for Nutrigenomics-derived Health CLAIMS Made on Food

Study objectives
1. The post-prandial metabolic and inflammatory biomarkers will be changed in obese compared with healthy, non-obese subjects.
2. Caloric restriction combined with n-3 polyunsaturated fatty acids (n-3 PUFA) supplementation will diminish the post-prandial metabolic and inflammatory responses.
3. The long-term supplementation with marine n-3 PUFA and low calorie diet will protect people from obesity-related complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Jagiellonian University Bioethical Committee, 25/06/2009, KBET/82/B/2009

Study design
Randomised placebo-controlled double-blind single-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Healthy and obese subjects

Interventions
1. Low calorie diet (1200–1500 kcal/day) or isocaloric diet combined marine n-3 PUFA (1.8 g/day) as oral supplements for 3 months
2. Low calorie diet (1200–1500 kcal/day) or isocaloric diet combined with oral placebo for 3 months

Blood samples will be taken at fasting and during postprandial lipids and glucose tolerance tests before and after the intervention.

Intervention Type
Supplement

Primary outcome measure
1. Changes in metabolic and inflammatory biochemical markers after 3 moths of diet and n-3 PUFA supplementation
2. Changes in lipids and glucose metabolism markers during postprandial state in obese patients before and after intervention
3. Changes in expression of genes in peripheral blood mononuclear cells before and after intervention

Secondary outcome measures
1. Changes in serum glucose-dependent insulinotropic peptide during postprandial period and after diet and n-3 PUFA supplementation
2. Changes in osteocalcin serum concentrations after diet and n-3 PUFA supplementation
3. Lipidomic analysis in serum before and after intervention
4. Changes in serum adipokines and cytokines after diet and n-3 PUFA supplementation
5. Association of gene polymorphisms with response to diet and n-3 PUFA supplementation

Overall study start date
01/09/2009

Completion date
28/02/2015

Eligibility

Key inclusion criteria
1. Age 25–65 years old
2. Body-mass index (BMI) 25–40 kg/m2
3. Not consuming fish oil or antioxidants
4. Willing to adhere to the study protocol
5. Able to provide written infomed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150 subjects

Total final enrolment
48

Key exclusion criteria
1. Age < 25 years old or > 65 years old
2. BMI < 25 kg/m2 or > 40 kg/m2

3. Diabetes or other endocrine disorders
4. Chronic diseases (e.g., gastrointestinal problems, kidney diseases, liver diseases or cardiovascular problems)
5. Pregnant or planning to become pregnant during the study
6. Use of prescribed medications to control inflammation, blood lipids and glucose
7. Use of fish oil or other diet supplements

Date of first enrolment
01/09/2009

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
Poland

Study participating centre
Jagiellonian University Medical College
Kopernika 15a
Krakow
Poland
31-501

Sponsor information

Organisation
Jagiellonian University Medical College

Sponsor details
Sw Anny 12
Krakow
Poland
30-006

Sponsor type
University/education

ROR
https://ror.org/03bqmcz70

Funder(s)

Funder type
Government

Funder Name
European Commission (Belgium)

Results and Publications

Publication and dissemination plan
Planning to submit manuscripts within 1 month and 6 months

Intention to publish date
05/03/2015

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/05/2015	15/02/2022	Yes	No
Results article		02/09/2021	08/03/2023	Yes	No
Results article		16/08/2022	08/03/2023	Yes	No