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Chronic omega-3 fatty acid supplementation in type 1 diabetes

Submission date
13/06/2017

Recruitment status
No longer recruiting

Registration date
27/06/2017

Overall study status
Completed

Last Edited
19/07/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetes is a chronic condition that causes blood sugar (glucose) levels to be uncontrolled. People with Type 1 Diabetes (T1D) have an increased risk of cardiovascular disease (CVD) (heart problems) which significantly reduces life expectancy and quality of life. Metabolic (chemical processes that convert food to energy) and vascular (heart and blood vessels) abnormalities which are typically present in T1D contribute heavily to this risk and can be impacted by diet. Foods that are normally consumed in the westernized world are predominantly high in carbohydrate (sugars, starches and fibres in food) and fat, which, in the presence of T1D, can cause a higher CVD risk. It has been found that a dietary supplement Omega-3 Fatty Acids (n3-FA) can reduce many CVD biomarkers in people with CVD and Type 2 Diabetes, but owing to a lack of available information, it is unknown whether such improvements can help people with T1D. The aim of this study is to examine the glycaemic (sugar), lipaemic (fat), inflammatory (swelling), and vascular (blood vessel) response of patients with T1D after consuming meals with high carbohydrates and fat following six months of n3-FA dietary supplement.

Who can participate?
Adults aged 18 to 65 years old with T1D

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a supplement containing fish oil that is taken by mouth daily for six months, followed by a 13 week washout period (where they do not take anything). During this time, participants attend the study centre four times, once before taking the supplement and again at three, six and nine months. They consume meals with high carbohydrates and high-fat content and provide blood samples and undergo non-invasive vascular heart) scans. Participants in the second group receive a placebo tablet containing corn oil taken by mouth daily for six weeks, followed by a 13 week washout period (where they do not take anything). During this time, participants attend the study centre four times, once before taking the supplement and again at three, six and nine months. They consume meals with high carbohydrates and high-fat content and provide blood samples and undergo non-invasive vascular heart) scans. Participants are assessed for their blood fat, glucose (sugar) levels and their vascular responses to see how the supplements affect their diabetes.

What are the possible benefits and risks of participating?
Participants may benefit from improving their management of their diabetes by receiving more refined recommendations for long-term and meal-time self-management. There are no notable risks with participating, however, participants may experience discomfort while providing blood samples.

Where is the study run from?
Leeds Beckett University (UK)

When is the study starting and how long is it expected to run for?
January 2017 to September 2019

Who is funding the study?
1. Leeds Beckett University (UK)
2. Nutricia Research Foundation (Netherlands)

Who is the main contact?
Dr Matthew Campbell

Contact information

Type(s)
Scientific

Contact name
Dr Matthew Campbell

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Additional identifiers

Integrated Research Application System (IRAS)
223639

Protocol serial number
IRAS 223639

Study information

Scientific Title

The therapeutic role of chronic omega-3 fatty acid supplementation in type 1 diabetes patients

Study objectives
1. Chronic supplementation with omega-3 fatty acids will lower the acute glycaemic and lipaemic disturbances associated with high-fat meal feeding.
2. Chronic supplementation with omega-3 fatty acids will lower the acute inflammatory and vascualr disturbances associated with high-fat meal feeding.
3. Chronic supplementation with omega-3 fatty acids will lower long-term markers of glycaemia, lipaemia, and inflammation disturbances following three-months washout.
4. Patient's attitudes towards n3-FA supplementation (compliance, adherence, facilitators, barriers, quality of life) will be positive.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/08/2017, North East - Tyne & Wear South Research Ethics Committee (HRA Jarrow, Room 001, Jarrow Business Centre, Rolling Mill Road, Jarrow, NE32 3DT, UK; +44 (0)207 1048 084; tyneandwearsouth.rec@hra.nhs.uk); REC ref: 17/NE/0244

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 1 Diabetes

Interventions
Participants are randomized (using a commuter automated programme) to one of two treatment groups (n3-FA supplementation or placebo control).

Arm 1 Supplementation: Participants receive the n3-FA supplement that comprises of ~4.0g.day of fish oil concentrate delivered via capsule ingestion (1.9g of EPA and 1.5g of DHA). This will be taken for a total of 26 weeks (six months) and is followed by a 13-week "washout" period. During this time, participants attend the laboratory on four occasions (a baseline visit, three months, six months, and nine months). Laboratory visits involve consuming mixed-macro-nutrient meals with high carbohydrate and high fat contents. During each visit blood samples are measured over an eight hour period to determine glycaemic, lipaemic, and inflammatory parameters, accompanied by periodic non-invasive vascular scanning techniques to assess vascular function.

Arm 2 Placebo Control: Participants receive the placebo which is a corn oil capsule for 26 weeks (six months) followed by a 13-week "washout" period. During this time, participants attend the laboratory on four occasions (a baseline visit, three months, six months, and nine months). Laboratory visits involve consuming mixed-macro-nutrient meals with high carbohydrate and high fat contents. During each visit blood samples are measured over an eight hour period to

determine glycaemic, lipaemic, and inflammatory parameters, accompanied by periodic non-invasive vascular scanning techniques to assess vascular function.

Intervention Type
Supplement

Primary outcome(s)
1. Blood glucose is measured using the Biosen C-Line at 30 minutes intervals throughout an 8-hour observation window at baseline, three, six and nine months
2. Blood lipid/fat is measured using the biochemical analysis (Elisa/Essay technique) at 30 minutes intervals throughout an 8-hour observation window at baseline, three, six and nine months

Key secondary outcome(s))
1. Inflammatory responses to mixed meals that are high in carbohydrate and fat, following n3-FA supplementation is measured using biochemical analysis (Elisa/Essay technique) at 30-minutes intervals throughout an 8-hour observation window at baseline, three, six and nine months
2. Vascular responses to mixed meals that are high in carbohydrate and fat, following n3-FA supplementation is measured using vascular imagining techniques at baseline, between 3-4 hours post-breakfast, and between 7-8 hours post-breakfast at baseline, three, six and nine months
3. Long-term resting glycaemic, lipaemic, inflammatory, and vascular responses to chronic n3-FA supplementation are measured using biochemical analysis (Elisa/Essay technique) at baseline, 3-months, and 6-months post intervention
4. Glycaemic, lipaemic, inflammatory, and vascular responses to chronic n3-FA supplementation following 3-months washout are measured using biochemical analysis (Elisa/Essay technique) and vascular scanning techniques at 9-months post intervention
5. Compliance and adherence towards n3-FA supplementation is measured using EHA and DHA from plasma/serum at baseline, 3-months, 6-months, and 9-months
7. Facilitators to n3-FA supplementation is measured using a non-validated questionnaire at baseline
8. Barriers to n3-FA supplementation is measured using a non-validated questionnaire at baseline
9. Quality of life is measured using a non-validated questionnaire at baseline, 3-months, 6-months, and 9-months post-intervention

Completion date
01/09/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 01/04/2020:
1. Male or female and aged 18-65 years old
2. Free from any diabetes-related complications (except background diabetic retinopathy)
3. Not known to be allergic or sensitive to fish, fish oil, or n3-FA products
4. Not known to have or have had documented atrial fibrillation
5. Not known to have documented liver problems or abnormal liver function
6. Will not be pregnant, planning to become pregnant within 12 months, or currently breastfeeding
7. Not known to have documented hematological abnormalities or experience heavy menstrual bleeding

8. Not taking prescribed medication knowing to interfere with study procedures
9. Treated with a stable insulin regimen composed of either:
9.1. A combination of slow/long-acting insulin glargine/detemir and a fast-acting insulin analogue lispro/aspart/glulisine
9.2. Continuous subcutaneous insulin infusion therapy (insulin pump therapy)
10. Have an HbA1c of <11% (97 mmol/mol)
11. Using the carbohydrate counting method for administering meal-time insulin

Previous inclusion criteria:
1. Male or female and aged 18-65 years old
2. Free from any diabetes-related complications (except background diabetic retinopathy)
3. Not known to be allergic or sensitive to fish, fish oil, or n3-FA products
4. Not known to have or have had documented atrial fibrillation
5. Not known to have documented liver problems or abnormal liver function
6. Will not be pregnant, planning to become pregnant within 12 months, or currently breastfeeding
7. Not known to have documented hematological abnormalities or experience heavy menstrual bleeding
8. Not taking any prescribed medication other than insulin
9. Treated with a stable insulin regimen composed of either:
9.1. A combination of slow/long-acting insulin glargine/detemir and a fast-acting insulin analogue lispro/aspart/glulisine
9.2. Continuous subcutaneous insulin infusion therapy (insulin pump therapy)
10. Have an HbA1c of <11% (97 mmol/mol)
11. Using the carbohydrate counting method for administering meal-time insulin

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
20

Key exclusion criteria
None.

Date of first enrolment

01/09/2017

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Beckett University
School of Sport
Headingley Campus
Leeds
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LS6 3QT

Sponsor information

Organisation
Leeds Beckett University

ROR
https://ror.org/02xsh5r57

Funder(s)

Funder type
University/education

Funder Name
Leeds Beckett University

Alternative Name(s)
Leeds Beckett

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Nutricia Research Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

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

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Matthew Campbell (m.d.campbell@leeds.ac.uk) (PI); raw anonymised data; available after publication for a total of 5 years; publicly available, for secondary data analysis or re-analysis including meta-analysis.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/08/2020	17/08/2020	Yes	No
Results article		03/06/2022	19/07/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V1	13/06/2017	01/04/2019	No	Yes