ISRCTN14530452 https://doi.org/10.1186/ISRCTN14530452

Measuring omega-3 fatty acid levels in terminal ileal content following four weeks of omega-3 fatty acid supplementation in patients with a temporary ileostomy

Submission date
05/02/2016

Recruitment status
No longer recruiting

Registration date
16/02/2016

Overall study status
Completed

Last Edited
10/10/2022

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Oily fish such as mackerel and sardines contain natural omega-3 fatty acids (O3FAs). They are commonly used as nutritional supplements in capsule form, with evidence suggesting numerous health benefits including improved cognitive performance, maintenance of a healthy heart and even possible anti-cancer effects. There is however little known about the amount of O3FA that enter an individual's large bowel after taking O3FA capsules. This is of particular interest as O3FAs may have numerous effects on the environment within the bowel, including anti-bowel cancer effects and possible changes in the type and balance of bacteria. The aim of our study is to measure the amount of O3FAs present in the stoma fluid after taking daily O3FA capsules for 4 weeks. We will also examine how O3FAs alter the balance of bacteria within the gut.

Who can participate?
Patients aged 50 or over with a temporary ileostomy (An ileostomy is where the bowel is diverted through an opening in the tummy [stoma] to collect waste products in a bag. They are performed to allow the bowel to heal after surgery to treat bowel cancer).

What does the study involve?
Participants are required to take two O3FA gelatin capsules twice a day with meals for 4 weeks. The O3FA capsules contain naturally occurring fatty acids found in oily fish such as mackerel and sardines. They are widely available for people to buy over the counter from pharmacies and supermarkets. The amount of O3FA within the stoma fluid is measured after taking the O3FA capsules for 4 weeks. Participants provide a stoma fluid sample at three separate visits over the 4 week period. At the start and end of the study participants also provide blood samples to measure the levels of O3FAs in the blood.

What are the possible benefits and risks of participating?
Although O3FA supplementation is associated with many health benefits, taking part in this study is unlikely to directly help participants. However, the results of the study may help plan

future research exploring the beneficial effects of O3FAs against bowel cancer. Participants may get some mild side-effects such as indigestion-type symptoms (including belching or change in stoma volume), at which stage they can decide whether to reduce or stop supplementation temporarily or permanently. Sometimes symptoms disappear if the daily dose is reduced. If participants stop taking the capsules during the 4 weeks, a stoma fluid sample and blood test is still required at the end of the study.

Where is the study run from?
St James University Hospital Leeds (UK)

When is the study starting and how long is it expected to run for?
October 2015 to June 2019

Who is funding the study?
Leeds Teaching Hospital Charitable Trust (UK)

Who is the main contact?
Dr Henry Watson
ugm3hsw@leeds.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Mark Hull

ORCID ID
http://orcid.org/0000-0001-7414-1576

Contact details
Level 9, Wellcome Trust Brenner
St James' University
Leeds
United Kingdom
LS9 7TF
+44 (0)113 343 8650
M.A.Hull@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
A pilot study to measure omega-3 fatty acid levels in terminal ileal content following four weeks of omega-3 fatty acid supplementation in patients with a temporary ileostomy

Study objectives
After 4 weeks of O3FA supplementation there is an increase in terminal ileal EPA and DHA levels compared with basal levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Leeds West Research Ethics Committee, 05/01/2016, ref: 15/YH/0547

Study design
Single-centre pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to requesta patient information sheet.

Health condition(s) or problem(s) studied
Participants with a loop ileostomy following anterior resection for colorectal cancer.

Interventions
All participants take two O3FA containing soft gel capsules twice daily with meals (total 1000 mg EPA and 1000 mg DHA daily) for 4 weeks. They are asked to provide a stoma fluid sample at 3 separate visits over the 4 week period. At the start and end of the study participants are also asked to provide a blood sample to measure the levels of O3FAs in their blood.

Intervention Type
Supplement

Primary outcome measure
Change in terminal ileal fluid EPA and DHA concentration at four weeks compared with baseline.

Secondary outcome measures
1. Change in percentage erythrocyte membrane content of EPA and DHA at four weeks compared with baseline.
2. Change in terminal ileal fluid EPA and DHA concentration within 24 hours of taking the first O3FA dose.
3. Tolerability and adverse events related to O3FA supplementation.

Overall study start date
01/10/2015

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Aged 50 years or over
2. Either gender
3. Temporary ileostomy fashioned at least 2 months prior to commencing study
4. Able to self medicate
5. A minimum period of 2 months availability for the study prior to planned ileostomy reversal

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
8

Total final enrolment
11

Key exclusion criteria
1. Seafood allergy
2. Ongoing and/or previous use (within 4 weeks of commencing the study) of other O3FA or cod-liver oil supplements
3. Previous small bowel resection
4. Metastatic colorectal cancer
5. Less than 4 weeks since any chemotherapy or radiotherapy
6. Inflammatory bowel disease or other intestinal disease (e.g. coeliac disease)

Date of first enrolment
10/02/2016

Date of final enrolment

30/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St James University Hospital
Leeds
United Kingdom
LS97TF

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Faculty Research Office
Room 10.110, Level 10, Worsley Building
Clarendon Way
Leeds
England
United Kingdom
LS2 9NL
+44 (0)113 343 7587
governance-ethics@leeds.ac.uk

Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Leeds Teaching Hospital Charitable Trust

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 09/06/2020:
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

Previous publication and dissemination plan:
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/05/2021	27/05/2021	Yes	No
Protocol file	version 3	27/06/2018	10/10/2022	No	No
HRA research summary			28/06/2023	No	No