

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/02/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/10/2022	Condition category Cancer	<input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

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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 request a 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

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Sponsor type

University/education

ROR

<https://ror.org/024mrx33>

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