

Randomised controlled trial of the effects of fish oil emulsion in total parenteral nutrition upon tumour vascularity in patients with hepatic colorectal metastases

Submission date 17/01/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 31/07/2006	Overall study status Completed	☐ Protocol
Last Edited 18/02/2014	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Ashley Dennison

Contact details
Department of Surgery
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW
+44 (0)116 249 0490
ashley.dennison@dial.pipex.com

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00942292

Clinical Trials Information System (CTIS)
2006-000044-71

Study information

Scientific Title

Study objectives

The hypothesis is that intravenous feeding supplemented with omega-3 fatty acids will reduce the tumour vascularity as assessed by dynamic contrast-enhanced Magnetic Resonance Imaging (MRI) in patients with hepatic colorectal metastases.

Ethics approval required

Old ethics approval format

Ethics approval(s)

No ethics approval as of 31/07/2006.

Primary study design

Interventional

Study design

Randomised, double-blind, controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hepatic colorectal metastases

Interventions

Intravenous feeding for three days either with or without (control) supplementation with omega-3 fatty acids.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Omega-3 fatty acids

Primary outcome(s)

To assess the effect of intravenous feeding supplemented with omega-3 fatty acids on tumour vascularity as assessed by dynamic contrast enhanced MRI.

Key secondary outcome(s)

1. Changes in serum levels of leukotrienes B5 and B4, Tumor Necrosis Factor alpha (TNF-a) and Interleukin 6 (IL-6). These are modulators of the inflammatory response
2. Measurements of omega-3 fatty acid levels and ratios in cellular membranes of blood

leukocytes (white blood cells)

3. Change in vascular endothelial growth factor receptor levels

4. Changes in Cyclooxygenase-2 (COX-2) activity in patients white blood cells (an enzyme which inhibits cancer cell death)

5. Omega-3/omega-6 ratios in subjects platelets and resected tumour

Completion date

01/08/2006

Eligibility

Key inclusion criteria

Patients with hepatic colorectal metastases, in whom the disease is assessed as amenable to curative resection will be eligible for the study. The inclusion criteria will be:

1. Ages 18-80

2. Able to give informed written consent

3. Diagnosis of resectable hepatic colorectal metastases on radiological and laparoscopic appearance (this trial is only assessing operative disease)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

All

Key exclusion criteria

Patients will be excluded from this trial if they have:

1. Malignant disease that is not thought to be potentially operable after laparoscopy

2. Patients already taking fish oil supplements (may interfere with results)

3. Patients already enrolled into other trials (e.g. of chemotherapy)

4. Hypersensitivity to fish, egg or soy protein or to any of the active substances or constituents in the lipid emulsion

5. Hyperlipidaemia

6. Severe blood coagulation disorders

7. Severe renal insufficiency (creatinine >200)

8. Any general contra-indications to infusion therapy pulmonary oedema, hyperhydration,

decompensated cardiac insufficiency

9. Any unstable medical conditions uncontrolled diabetes mellitus, acute myocardial infarction, stroke, embolic disease, metabolic acidosis, sepsis, pancreatitis

Patients meeting the above criteria are excluded as they represent inoperable disease, cases where the results would be invalid (already taking fish oil supplements), contraindications to lipid infusion and unstable medical conditions.

Patients will also be excluded if they have any contraindications to MRI scanning:

1. Cardiac pacemaker
2. Other ferromagnetic metal implants not authorised for use in MRI such as certain types of cerebral aneurysm clips
3. Claustrophobia
4. Body weight or circumference beyond the MRI scanners capacity

Date of first enrolment

01/03/2006

Date of final enrolment

01/08/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Surgery

Leicester

United Kingdom

LE5 4PW

Sponsor information

Organisation

University Hospitals of Leicester NHS trust (UK)

ROR

<https://ror.org/02fha3693>

Funder(s)

Funder type

Industry

Funder Name

BBraun Melsungen AC (Germany)

Results and Publications

Individual participant data (IPD) sharing plan**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	results	07/05/2013		Yes	No
Results article	results	01/06/2013		Yes	No