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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

Registration date
31/07/2006

Overall study status
Completed

Last Edited
18/02/2014

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

ClinicalTrials.gov (NCT)
NCT00942292

Protocol serial number
N/A

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.

Study design
Randomised, double-blind, controlled trial

Primary study design
Interventional

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