Pilot study on the effects of oral immunonutrition on the quality of life in patients receiving palliative treatment for oesophageal and proximal gastric cancer.

Submission date 30/09/2005	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 30/09/2005	Overall study status Completed	 Statistical analysis plan Results
Last Edited 05/03/2020	Condition category Cancer	 Individual participant data Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0055143763

Study information

Scientific Title

Pilot study on the effects of oral immuno-nutrition on the quality of life in patients receiving palliative treatment for oesophageal and proximal gastric cancer.

Study objectives

Does EPA supplementation affect patients' quality of life and survival with known esophageal and proximal gastric cancer who are receiving non-curative treatments?

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Quality of life

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 Cancer: Gastrointestinal

Interventions

Patients, after obtaining informed consent, are randomly assigned one of the nutritional supplements, both of similar calorific value but one contains EPA.

Intervention Type Other

Phase Not Specified

Primary outcome measure

Measurements of QoL, weight etc. are made at monthly interval, follow-up until death.

Secondary outcome measures Not provided at time of registration

Overall study start date 01/06/2002

Completion date 30/06/2004

Eligibility

Key inclusion criteria

Patients with histologically diagnosed oesophageal or proximal gastric cancer that are not receiving curative treatment.

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants Not provided at time of registration

Key exclusion criteria Not provided at time of registration

Date of first enrolment 01/06/2002

Date of final enrolment 30/06/2004

Locations

Countries of recruitment England

United Kingdom

Study participating centre North Cumbria Acute Hospitals NHS Trust Carlisle United Kingdom CA2 7HY

Sponsor information

Organisation Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type Government

Funder Name North Cumbria Acute Hospitals NHS Trust (UK)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration