# The effect of combined n-3 polyunsaturated fatty acid and antioxidant dietary supplements on Crohn's disease & the associated osteoporosis, malnutrition and morbidity

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>			
23/01/2004		☐ Protocol			
Registration date	Overall study status	Statistical analysis plan			
23/01/2004	Completed	[X] Results			
Last Edited	Condition category	[] Individual participant data			
05/07/2018	Digestive System				

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Tim Trebble

#### Contact details

Institute of Human Nutrition Level C Southampton General Hospital Tremona Road Southampton United Kingdom SO16 6YD +44 (0)23 80 796 317 abc@123.com

# Additional identifiers

EudraCT/CTIS number

IRAS number

#### ClinicalTrials.gov number

# **Secondary identifying numbers** SEO124

# Study information

#### Scientific Title

The effect of combined n-3 polyunsaturated fatty acid and antioxidant dietary supplements on Crohn's disease & the associated osteoporosis, malnutrition and morbidity

#### **Study objectives**

Crohn's disease is a chronic inflammatory disease of the bowel, frequently affecting young adults, and occurring in approximately 80 per 100 000 population. Crohn's has many systemic complications, in particular osteoporosis, cachexia, anorexia, all of which contribute to acute and chronic morbidity, frequent hospital admissions and high health costs. Estimates of the annual average costs of treating one Crohn's patient vary between £2652 and £5856 depending on local costs. This amounts to between £212160 and £468480 per 100000 population per year.

Effective therapies in Crohn's are currently restricted to immunosuppressants, such as corticosteroids which can themselves be associated with such side effects as osteoporosis. There is, therefore an argent need for safe, effective, maintenance anti-inflammatory interventions.

We propose the first major clinical trials of combined dietary supplements in Crohn's disease hypothesising that n-3 PUFA and antioxidant cosupplementation will:

- 1. Reduce clinical disease activity in Crohn's and improve quality of life.
- 2. Modify bone turnover in favour of bone formation.
- 3. Reduce the systematic inflammatory response (measured by inflammatory markers) and will lead to an increase in dietary intake and improvement in nutritional status.

# 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)

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Digestive system diseases: Inflammatory bowel disease; Musculoskeletal diseases: Osteoporosis

#### **Interventions**

- 1. The dietary intervention consists of: 9 capsules per day of (Maxepa) fish oil (1.62 g of eicosapentaenoic acid, 1.08 g of docosahexanoic acid) and 1 capsule per day of antioxidant vitamins containing selenium 200 ug (reference nutrient intake [RNI] 75 ug/day) manganese 3 mg (UK intake 5.5 mg/day), vitamin A 450 ug (RNI 700 ug) vitamin E 30 ug (average UK intake 5-7 mg), vitamin C 90 mg (RNI 40 mg).
- 2. Placebo will consist of 9 capsules containing olive oil and 1 containing sugar. The placebos are indistinguishable from the active treatments.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

Maintenance of disease remission, as defined by an absence of disease relapses (recognised quantitative increase in Crohn's disease activity index (CDAI) score of 100 to an absolute value of greater than 150) during the 6 month intervention period.

#### Secondary outcome measures

- 1. Biochemical markers of bone turnover (osteocalcin and deoxypridinoline)
- 2. Markers of inflammation (1L-1, 1L-6 and TNF-a)
- 3. Quality of life score
- 4. Nutritional status

#### Overall study start date

01/05/2000

#### Completion date

01/05/2002

# Eligibility

#### Key inclusion criteria

Male and female patients aged between 18 and 75, with a diagnosis of Crohn's disease based on endoscopic, histological or radiological investigation.

Patients will be:

- 1. At high risk of active disease based biochemical markers (i.e. a C-reactive protein [CRP] >6.9 or erythrocyte sedimentation rate [ESR] >20) and history (disease relapse within the last 2 years with Crohn's Disease Activity Index [CDAI] >150).
- 2. Currently in remission and not requiring use of oral or intravenous steroids or other immunosuppression (with the exception of azathioprine) within the last month.

## Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

# Target number of participants

Added December 2008: 61

#### Key exclusion criteria

Patients with no evidence of recurrent disease following bowel resection; patients with other bone disorders e.g. hyperparathyroidism; or use of therapeutic agents known to affect bone metabolism, e.g. hormone replacement therapy (HRT), bisphosphonates, calcium and vitamin D supplements.

## Date of first enrolment

01/05/2000

#### Date of final enrolment

01/05/2002

# Locations

#### Countries of recruitment

England

United Kingdom

# Study participating centre Institute of Human Nutrition

Southampton United Kingdom SO16 6YD

# Sponsor information

#### Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

## Sponsor details

The Department of Health 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.doh.gov.uk

# Funder(s)

## Funder type

Government

#### Funder Name

NHS Executive South East (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

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Results article	results on composition and function of circulating mononuclear cells	01/11 /2004		Yes	No
Results article	results on the response of bone turnover	01/08 /2005		Yes	No