

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

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Submission date 23/01/2004 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 23/01/2004 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 05/07/2018 | Condition category Digestive System | <input type="checkbox"/> 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

Protocol serial number

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 argment 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

Study type(s)

Not Specified

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(s)

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.

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

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)

Funder(s)**Funder type**

Government

Funder Name

NHS Executive South East (UK)

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 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 |