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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
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
05/07/2018

Condition category
Digestive System

[_] 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

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)

Not Specified

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
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Sponsor type
Government

Website
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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