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A comparison of a new formulation feed compared with the standard use of emsogen as primary enteral nutrition therapy to attain remission in paediatric Crohn's Disease

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
31/05/2019

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
N0206135454

Study information

Scientific Title
A comparison of a new formulation feed compared with the standard use of emsogen as primary enteral nutrition therapy to attain remission in paediatric Crohn's Disease

Study objectives
Is the percentage of patients who will take the trial (polymeric) feed orally significantly greater than the percentage who will take the standard (elemental) feed orally, during a six week (42 day) treatment period?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added February 2008:
Liverpool Local Research Ethics Committee granted 9th Feb 2004. Permission to continue a two year retrospective follow up granted 17th August 2006 extending the end date to April 2008. REC ref. 03/12/224/C

Study design
Randomised controlled, single blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Digestive System: Crohn's disease

Interventions
Polymeric feed vs standard elemental feed

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
The percentage of patients who took the trial (polymeric) feed orally compared to the percentage that took the standard (elemental) feed orally during a six-week (42 day) treatment period.

Secondary outcome measures
Added February 2008:

1. Paediatric Crohns Disease Activity Index (PCDAI): The primary outcome measure of this study is the evaluation of these enteral diets to induce remission in acute Crohns disease. Clinical remission is defined as a (PCDAI) <10. PCDAI will be calculated from assessment of the degree of abdominal pain, stool pattern, general well being, presence of extra-intestinal manifestations, physical examination findings, weight and height, haematocrit, ESR and albumin. PCDAI will be calculated prior to entry in the trial and at 6 weeks to assess the efficacy of the enteral feed.
2. Nutritional Status: Weight will be measured before and after the period of enteral feeding. Standard deviation (Z) scores will be calculated, using computer software designed for this purpose, to assess changes in the nutritional status of the participants.
3. Antioxidant Status: Plasma and red blood cell fatty acid profile measures of antioxidant status (Vitamins A C and E assay and Isoprostanes) see appendix IV of the protocol for background information.
4. Stool Analysis: Stool specimens will be examined for enteric pathogens, parasites and Clostridium difficile toxin at baseline only to ensure the patient does not have a gastrointestinal infection. Faecal calprotectin (Appendix V of the protocol) will be measured at baseline and at the end of the study in order to assess the degree of neutrophil activation and inflammation within the gut, an indicator of Crohns disease activity.

Overall study start date
01/03/2004

Completion date
30/04/2008

Eligibility

Key inclusion criteria
Paediatric patients (male and female up to 16 years of age) on first presentation of Crohn's disease. 20 patients will be randomised into each group (total n = 40) upon diagnosis.

Participant type(s)
Patient

Age group
Child

Upper age limit

16 Years

Sex
Both

Target number of participants
40

Total final enrolment
34

Key exclusion criteria
Added February 2008:
1. Under 5 years
2. History of Crohns disease or colitis
3. Current use of steroids or other anti-inflammatory medication
4. Colonic Crohns disease without involvement of the small bowel
5. Females who are pregnant or breast-feeding
6. Severe disease including:
6.1 Intestinal perforation
6.2 Significant intestinal obstruction
6.3 Abdominal abscess
6.4 Toxic mega colon
6.5 Severe gastrointestinal hemorrhage
6.6 Mid-jejunal fistulas which preclude the use of enteral nutrition
7. Remaining small bowel less than 180 cm (6 feet) with an ileostomy
8. Need of TPN because of short bowel syndrome
9. Clinically significant disease (other than defined active Crohns disease) that would interfere with subjects compliance to the protocol requirements or with the Investigators interpretation of the study findings
10. Evidence of enteric pathogens or toxin i.e. Clostridium difficile
11. Previous enrolment in the study protocol

Date of first enrolment
01/03/2004

Date of final enrolment
30/04/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
RLC NHS Trust
Liverpool

United Kingdom
L12 2AP

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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United Kingdom
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Royal Liverpool Children's 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results				No	No
Results article	results	01/02/2012	31/05/2019	Yes	No