

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	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 31/05/2019	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Joanne Grogan

Contact details
RLC NHS Trust
Alder Hey
Eaton Road
Liverpool
United Kingdom
L12 2AP
+44 (0)151 252 5231
Jo.Grogan@rlch-tr.nwest.nhs.uk

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled, single blind study

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

16 Years

Sex

All

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

United Kingdom

England

Study participating centre

RLC NHS Trust

Liverpool

United Kingdom

L12 2AP

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Royal Liverpool Children's NHS Trust (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	01/02/2012	31/05/2019	Yes	No
Abstract results				No	No