

# 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

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<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 31/05/2019	<b>Condition category</b> Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## 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

**Study design**

Randomised controlled, single blind study

**Primary study design**

Interventional

**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?
<a href="#">Results article</a>	results	01/02/2012	31/05/2019	Yes	No
<a href="#">Abstract results</a>				No	No