

## ABOUT EXCLUSIVE ENTERAL NUTRITION

Exclusive Enteral Nutrition (EEN; nutrition formula) is has been an established way to induce remission in pediatric Crohn's Disease. By eliminating possible trigger foods, EEN is able to promote gut healing through different mechanisms.

**If you qualify and want to meet the team, please contact below.**

**CROHN'S DISEASE & EXCLUSIVE ENTERAL NUTRITION**



### Our Study

The Exclusive Enteral Nutrition in Crohn's Disease Study is the first clinical research study to investigate the combined use of a nutritional formula with Corticosteroids (CS) in order to decrease the activity of CD and improve quality of life. The trial is being led by Dr. M Ines Pinto-Sanchez, Dr. David Armstrong, the Gastroenterology team at McMaster University and the Farncombe Digestive Disease Research Institute. This study is supported by Crohn's and Colitis Canada and Nestlé Canada.

### Contact information.



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**A NUTRITION FORMULA TO INDUCE REMISSION IN CD**

## OUR GOALS

While EEN is used to induce remission in pediatric cases of CD, its use in adults is much less studied. This is the **first pilot study** to assess the use of EEN together with CS as a means of inducing remission in adults. We think EEN+CS will be **more effective** than CS alone in inducing remission and that a short course of CS in tandem with nutritional formula will have a similar efficacy than the standard course of CS, with a **reduced number of adverse events**. We also would like to test whether nutritional formula will lead to beneficial changes in the intestinal bacteria, gastrointestinal transit and inflammatory burden.

## Do I Qualify?

We are looking for adults **aged 18-75**, diagnosed with CD who are **flaring**, and are about to start **Prednisone** prescribed by their doctor.

Unfortunately, we are not able to accept patients with the following criteria:

- Treated with antibiotics or probiotics in the last 30 days.
- Used prednisone in the last 30 days.
- Currently using EEN.
- Short Gut.
- Started or changed immunosuppressant or biologic medication in the last 90 days.
- Started or changed 5-ASA medication in last 30 days.
- Pregnancy or lactation.

## Frequently Asked Questions:

Q: What is a clinical trial?

A: Clinical trials are medical research study that investigates a hypothesis regarding the safety and/or efficacy of one or more treatment options.

Q: What kind of oversight is there for these trials?

A: In order to protect participants health and rights, all studies are reviewed and approved by an institutional Review Board or Ethics Committee.

Q: How will my safety be monitored?

A: During this study it is possible that your symptoms may not improve, may worse, or that you develop unexpected reactions to the treatments. You will be carefully monitored, and the study doctor can give you "rescue" medication if your symptoms persist or worsen. We may discontinue treatment if needed, and patients are able to withdraw from the study at any time.

Q: What is in the Nutritional Formula?

A: We obtain our nutritional formula from Nestlé Health Science, developed under the name **Modulen IBD®**. Modulen IBD® is a powdered formula designed to meet the specific nutritional needs of people with CD. To prepare the formula, water needs to be added to the powder to obtain a complete nutritional liquid to be taken orally, replacing meals and snacks. The formula will be provided to participants at no cost.

Modulen IBD® is gluten free, but contains milk and lactose. It is not kosher certified.

## Participants will be sorted randomly into 1 of 3 treatment arms:

1

**Regular Diet +  
Standard Course of  
Corticosteroids**

2

**Nutritional Formula +  
Standard Course of  
Corticosteroids**

3

**Nutritional Formula +  
Short Course of  
Corticosteroids**

## In-Person Visits

- The treatment length is 6 weeks, with a total trial length of 10 weeks.
- There will be 4 in-person visits during which physical examinations, laboratory tests, and questionnaires will be administered.
- Each visit will take approximately an hour and a half.
- Parking tickets and small reimbursements for study visits will be provided at the end of the study.
- **We hope that our results will lead to a more effective way to induce remission in active CD and reduce adverse events associated with CS.**