Call Toll-free 1-800 856-7842 or 828-254-0881 with Extension listed

Name of Study: **Efficacy of CROWN in Repair and Maintenance of the Intestinal Mucosa in Patients with CD Receiving Anti-TNF Therapy (PIONEER-CD)-(Nestle/Robarts)**

LINK: https://clinicaltrials.gov/ct2/show/NCT02793778?term=robarts+pioneer+Crohn%27s&rank=1

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Summary: A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Effectiveness of a Nutritional Intervention in Improving the Intestinal Mucosal Health Status in Subjects with Crohn's Disease (CD) Receiving Induction Anti-TNF Therapy.

Enrollment Begins: 3Q2016

Enrollment Ends: 3 year enrollment

The primary objective of the study is to evaluate the effectiveness of an orally administered medical food, hereby referred to as 'CROWN,' in subjects with CD and incomplete healing of the intestinal mucosa to support the standard of care (SOC) in the repair and maintenance of the intestinal mucosa over a 24 week period. For the purpose of this study, SOC is defined as completion of induction therapy with an anti-TNF agent within 24 weeks of its initiation. A regular diet for the individual subject should be maintained.

Inclusion:

- Adults (18-75 years of age) with a known history of symptomatic CD confirmed by endoscopy or radiology• CDAI score ≤ 300
- Active endoscopic disease (SES-CD score > 6) documented during the study screening phase or SES-CD score = 4 if isolated ileal disease
- Initiation of induction of infliximab or adalimumab therapy within 24 weeks prior to randomization as part of standard care (induction must be completed prior to randomization)
- Able to consume oral nutrition for up to 24 weeks consisting of two 4 oz (120 ml) servings daily
- Able to understand the informed consent process, willing to follow study instructions and likely to complete all required visits and procedures, including the use of an electronic device to collect study data, home

computer or tablet and internet access to complete online food frequency questionnaire, and undergo 2 endoscopies in a 6 month period

Exclusion:

- If female, subject is pregnant, nursing, or planning to become pregnant during the study period or is of childbearing potential and unable or unwilling to use a reliable form of contraception during the study
- Fistula known to be contributing to diarrhea
- Recent or current history of bowel obstruction
- Stricturing disease with evidence of bowel dilation proximal to stricture on imaging
- Anticipated need for gastrointestinal surgical therapy in the next 6 months
- Current treatment with a systemic corticosteroid at dose greater than 20 mg of prednisone (or equivalent) at screening
- Current treatment with a topical corticosteroid therapy at screening
- Current treatment with rectal steroids at screening
- Change in any antimetabolite therapy within 8 weeks prior to randomization.
- Current treatment with antibiotics for CD (ciprofloxacin, metronidazole) at screening
- Current ostomy
- Serious infection, neoplasia or other medical conditions which would interfere with participation in the study, in the opinion of the investigator
- Evidence of Clostridium difficile infection in the previous 4 weeks
- History of non-compliance with clinical protocols
- Active participation in another CD trial or received an investigational product within the past 4 weeks
- Diagnosis of celiac disease
- Known sensitivity to whey or soy protein
- In the Investigator's opinion, subject has any condition or situation which makes the subject unsuitable for study participation, may put the subject at significant risk, or may confound the study results