

Comparative Effectiveness of Specific Carbohydrate and Mediterranean Diets to Induce Remission in Patients with Crohn's Disease (DINE-CD)

Study & Project Aims

Aim 1: Compare effectiveness of 2 diets to induce symptomatic and clinical remission in patients with active Crohn's disease (CD)

Aim 2: Compare effectiveness of 2 diets to reduce mucosal inflammation

Intervention: Participants will be randomized to follow the Specific Carbohydrate Diet (SCD) or Mediterranean Style Diet (MSD) for 12 weeks

PCORNet Benefits:

- Collaborations with CCFA Partners PPRN and Mid-South CDRN will enhance patient recruitment
- Study operations data will be reported to PCORnet to help future projects
 - i.e. amount of time to:
 - IRB approval
 - subcontracts with clinical sites
 - first patient

Methods

- Open label, multi-center, randomized clinical trial
- Visits at baseline, 6 and 12 weeks
- Food adhering to assigned diet delivered to patients' homes for 6 weeks
- Patients follow diet on their own weeks 7-12
- Daily short CD Activity Index (sCDAI) surveys emailed or texted to participants
- Primary outcomes assessed at 6 weeks:
 - sCDAI to assess remission
 - Fecal calprotectin to assess mucosal inflammation
- Collaborators:
 - CCFA Partners PPRN
 - Global Healthy Living Fdn
 - Mid-South CDRN – will identify and contact potential patients at UNC and Vanderbilt
 - ImproveCareNow
 - UNC Center for GI, Biology and Disease

Research Objectives

- High quality studies of dietary patterns and the natural history of CD are lacking¹
- Need for therapies that do not suppress the immune system
- This study responds to the top study topics proposed by the CCFA Partners PPRN (see table below)
- Our objective is to find an effective nutrition therapy to treat CD that may serve as an alternative or adjunct to immunosuppressant drugs



IMPROVECARENOW

Question proposed by PPRN Patient Governance Council Members	Votes in Support
Compare individuals who manage their disease with medications and those who manage their disease with popular diets in the IBD community, such as the SCD	131
Research the validity of VSL#3 probiotic in controlling flare ups or as a factor in remission	96
Compare symptoms of IBD patients who consume dairy and those who avoid dairy	80

Unpublished data, CCFA Partners PPRN, 2015

References:

- Peyrin-Biroulet L, et al. Am. J. Gastroenterol. 2010;105(2):289-297

Initial Findings and/or Hypothesis

Progress to date:

- Clinical sites selected and contracting underway
 - Food vendor under contract
 - Database under development
 - Protocol under IRB review
 - Patient materials being developed
- Patient stakeholder involvement:**
- Input on protocol
 - Developing education materials for participants

Hypothesis:

Patients following the Specific Carbohydrate Diet are more likely to have resolution of CD symptoms

DISCLOSURES: None

FUNDING / ACKNOWLEDGEMENTS

This work was [partially] supported through a Patient-Centered Outcomes Research Institute (PCORI) Program Award (DEMO-1507-31465). All statements in this poster, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of PCORI, its Board of Governors or Methodology Committee

CONTACT INFORMATION

Erin Gilroy, Project Manager:

215-746-4218 egilroy@mail.med.upenn.edu