ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 06/05/2014

ClinicalTrials.gov ID: NCT01676324

Study Identification

Unique Protocol ID:	H12-01499
Brief Title:	FOCUS: The Future of Fecal Calprotectin Utility Study for the Diagnosis and Management of Inflammatory Bowel Disease (IBD)
Official Title:	FOCUS: The Future of Fecal Calprotectin Utility Study for the Diagnosis and Management of IBD
Secondary IDs:	

Study Status

Record Verification:	June 2014
Overall Status:	Completed
Study Start:	September 2012
Primary Completion:	March 2013 [Actual]
Study Completion:	September 2013 [Actual]

Sponsor/Collaborators

Sponsor:	University of British Columbia
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: H12-01499 Board Name: Providence Healthcare Research Institute Board Affiliation: UBC-PHC Research Ethics Board Phone: 604-682-2344 Email: lfedoroff@providencehealth.bc.ca
Data Monitoring?:	Yes
Plan to Share Data?:	
Oversight Authorities:	Canada: Health Canada

Study Description

Brief Summary: Hypothesis:

Fecal Calprotectin will be useful in guiding the diagnosis and management of patients with Inflammatory Bowel Disease. Fecal Calprotectin can be utilized as an alternative to colonoscopy in the management of patients with Inflammatory Bowel Disease.

Objectives:

By means of a survey from the ordering physician we would assess:

Primary Endpoint

1. The Percentage of time that the Fecal Calprotectin result caused the physician to change the management of a patient.

Secondary Endpoints

1. To determine if the Fecal Calprotectin result influenced the number of endoscopies performed
2. To correlate how well the Fecal Calprotectin correlates with Endoscopic findings when endoscopy was performed.
3. To assess the correlation between the Fecal Calprotectin level and symptoms as measured by the Harvey Bradshaw index or the partial Mayo Score (or full Mayo Score depending if endoscopy was performed).

Detailed Description: Patients will be identified as eligible by the attending Gastroenterologist during the course of a usual consultation. Patients will be referred to the research nurse in the doctor's office for further information regarding the study and informed consent will be obtained by the research nurse.

Upon enrollment, the physician or the research nurse will complete an online requisition form with a unique code which will provide the baseline data. The patient will be provided with the Easy Sampler™ collection kit and instructions on the use of this kit and location on where to send the specimen.

The nurse will then send an email to the research nurse in the originating physician's office with the result of the calprotectin assay. The research nurse will review the result with the physician. After physician review, either the physician or the research nurse will then complete a follow up survey online.

After completion of the assays and surveys, the data will be tabulated electronically from the online website and analyzed by the PI and/or co-investigators.

Conditions

Conditions: Inflammatory Bowel Disease
Crohn's Disease
Ulcerative Colitis

Keywords: Fecal Calprotectin

Study Design

Study Type: Observational

Observational Study Model: Cohort

Time Perspective: Prospective

Biospecimen Retention: None Retained

Biospecimen Description:

Enrollment: 289 [Actual]

Number of Groups/Cohorts: 1

Groups and Interventions

Groups/Cohorts	Interventions
Inflammatory Bowel Disease Those with Inflammatory Bowel Disease (known) and those with no Inflammatory Bowel Disease (not previously diagnosed)	

Outcome Measures

Primary Outcome Measure:

1. Percentage of time that Fecal Calprotectin result caused the physician to change the management of a patient. [Time Frame: one year] [Safety Issue: No]
   The utility of the test will be assessed by comparing the proportion of time the test altered management for each of the two groups (IBD present vs. IBD absent). The groups will be compared using paired t-tests and McNemar's test as appropriate. Multivariate analysis will be used to assess the impact of the baseline variables on the test utility.

Eligibility

Study Population: Patients will be those age 19 or older seen by community and academic gastroenterologists and may be referred for Fecal Calprotectin testing at the discretion of the Gastroenterologist.

Sampling Method: Non-Probability Sample

Minimum Age: 19 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Subjects must be at least 19 years of age or older, they must be able to read and provide written consent in English.

Subjects will have gastrointestinal symptoms or be known to have Inflammatory Bowel Disease whereby the clinician feels that obtaining Fecal Calprotectin may be useful in the care of the patient. Patients must be able to collect a feces sample and return it for analysis within 3 days

Exclusion Criteria:

- Known Ischemic colitis, infectious enteritis or colitis, known colorectal cancer, history of extensive bowel resection, ostomy, current daily use of NSAIDs (aspirin, ibuprofen, naproxen, etc) or the inability to collect sample and return it within 3 days

Contacts/Locations

Study Officials: Brian Bressler, MD
Study Principal Investigator

Department of Medicine, Division of Gastroenterology, UBC

Locations: Canada, British Columbia
GI Research Institute (GIRI)
Vancouver, British Columbia, Canada, V6Z 2K5

References

Citations: Sutherland AD, Gearry RB, Frizelle FA. Review of fecal biomarkers in inflammatory bowel disease. Dis Colon Rectum. 2008 Aug;51(8):1283-91. doi: 10.1007/s10350-008-9310-8. Epub 2008 Jun 10. Review. PubMed 18543035

Gisbert JP, Bermejo F, Pérez-Calle JL, Taxonera C, Vera I, McNicholl AG, Algaba A, López P, López-Palacios N, Calvo M, González-Lama Y, Carneros JA, Velasco M, Maté J. Fecal calprotectin and lactoferrin for the prediction of inflammatory bowel disease relapse. Inflamm Bowel Dis. 2009 Aug;15(8):1190-8. doi: 10.1002/ibd.20933. PubMed 19291780

Schoepfer AM, Beglinger C, Straumann A, Trummler M, Vavricka SR, Bruegger LE, Seibold F. Fecal calprotectin correlates more closely with the Simple Endoscopic Score for Crohn's disease (SES-CD) than CRP, blood leukocytes, and the CDAI. Am J Gastroenterol. 2010 Jan;105(1):162-9. doi: 10.1038/ajg.2009.545. Epub 2009 Sep 15. PubMed 19755969

[Study Results] Keohane J, O'Mahony C, O'Mahony L, O'Mahony , Quigley EM, Shanahan F. Irritable Bowel Syndrome-Type Symptoms in Patients With Inflammatory Bowel Disease: A Real Association or Reflection of Occult Inflammation? Am J. Gastroenterol. 2010 Apr. 13;15(8)1789-94

Links:

Study Data/Documents: