University of Michigan Health System

IBD Patient News

Winter 2015 U-M Division of Gastroenterology

TRACKING PATIENTS, PREDICTING FLARES

Previous data suggests that steps, sleep, and heart rate change before clinical flares of IBD. We are interested in tracking patients with Crohn's disease who are currently in remission on Humira, using the Fitbit HR, as part of new clinical trial we are conducting here at U of M.

The title of the study is "Calprotectin-Directed Humira® Maintenance Therapy, a Double-blind, Double-dummy, Randomized Controlled Trial in Crohn's Disease (CADHUM)" (HUM00048376). Patients want to know if they can stop taking their medication while in remission, without risk of a flare. The purpose of this study is to see if we monitor you (steps, sleep, heart rate), along with looking at changes in your stool samples (fecal calprotectin levels), we can safely stop the maintenance medication Humira for up to 46 weeks, OR add as-needed dosing only, and keep you in remission. We would analyze the data from the Fitbit to detect patterns that would predict the risk of flare.

We are currently enrolling patients for this study! If you have Crohn's disease, have been in remission on Humira for at least 6 months and have considered stopping your medication, you may be eligible to participate. You can email higginsSCteam@umich.edu or call Katy at 734-615-4843 for more information.

IBD NEWS YOU CAN USE:

Why Do Patients With IBD Get Weird Rashes?

The skin is one of the most commonly affected organ systems in individuals suffering from Crohn's disease and ulcerative colitis. According to the CCFA (Crohn's and Colitis Foundation of America), approximately 5% of people with IBD are affected by skin disorders associated with IBD. Commonly seen skin disorders of IBD patients include erhthema nodosum (little red bumps usually on or around shins, ankles, and arms), pyoderma gangrenosum (pus-filled blisters or ulcers often around the shins, ankles, or arms), and aphthous stomatitis (mouth ulcers or canker sores). While it is not known exactly what causes some individuals with IBD to develop skin disorders, researchers believe that over-activity of the immune system commonly seen in patients with IBD along with a disturbance in the relationship between immune system defense and tolerance systems may be to blame.

While there is no way to prevent extra-intestinal skin manifestations associated with IBD, often times treating the intestinal symptoms usually improves extra-intestinal manifestations also. Common treatments include corticosteroids, antibiotics such as metronidazole and tetracycline, methotrexate, azathioprine, and sulfasalazine. Ultimately, it is important for your healthcare provider to be alerted to skin manifestations for evaluation and treatment.

Ongoing IBD Clinical Studies

University of Michigan Health System

VISIT OUR WEBSITE:

U-M Inflammatory Bowel Disease Program

www.med.umich.edu/IBD

Title: OCTAVE for UC **Drug: Tofacitinib (CP-690,550) – oral medication**

This is a phase 3 study for subjects with moderately to severely active ulcerative colitis. This medication is a JAK inhibitor which reduces many cytokines, rather than blocking one cytokine at a time, as is the case of anti-TNF drugs.

Titile: HICKORY for UC **Drug: Etrolizumab, injection under the skin**

This is a phase 3 study for patients with moderate to severe active ulcerative colitis. This medication is an anti-integrin β7 therapy that regulates white blood cell trafficking in the lining of the intestines.

Title: Abbvie M-14 for Crohn's and UC **Drug: Humira, injection under the skin**

Crohn's: A phase 3 study for subjects with moderately to severely active Crohn's disease to evaluate the efficacy and safety of two Humira induction regimens followed by standard maintenance therapy with Humira.

UC: A phase 3 study for subjects with moderately to severely active ulcerative colitis to evaluate a high dose Humira induction regimen versus a standard dose induction regimen, followed by high dose versus standard dose maintenance therapy.

Title: CT-P13 for Crohn's **Drug: Generic Remicade, infusion**

This is a phase 3 study for patients with moderate to severely active Crohn's disease to evaluate the safety and effectiveness of CT-P13 (a generic form of Remicade) versus Remicade. Patients will be randomized to receive either CT-P13 or Remicade (no placebo) for up to 54 weeks.

Title: CADHUM for Crohn's **Drug: Humira, injection under the skin**

In this study, we are testing whether patients who are in remission on Humira can stop their medication and only be re-dosed if their inflammatory markers begin to increase. This requires following participants very closely, with fecal calprotectin/CRP testing every 3 months. If there is a rise in the inflammatory markers, we will treat these patients with loading doses of Humira before symptoms occur to see if we can prevent flares.

Title: GEM Project **(observational study)**

Our goal for this study is to follow healthy brothers, sisters and children of patients with Crohn's disease to try and identify the different factors that may lead to the development of this disease.

WHO CAN PARTICIPATE? You can participate in this study if you are generally healthy, between the ages of 6 and 35, and have a sibling or parent that has been diagnosed with Crohn's disease.

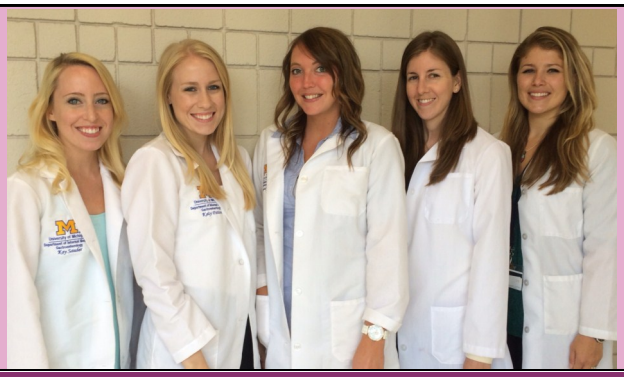
WHAT IS INVOLVED: Your participation would involve one visit where we would ask you to complete 3 questionnaires and give us a blood, urine, and stool sample. You would then be contacted by telephone every 6 months for up to 6 years to ask if there are any changes to your health. You will be compensated $20 to thank you for your participation.

Contact the UM IBD Clinical Trial Team!

higginsSCteam@umich.edu

734-615-4843

734-647-2564



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