University of Michigan Health System

IBD Patient News

Spring/Summer 2015 U-M Division of Gastroenterology

New IBD School Videos Now Available Online!

New Videos Include:

201: Urgency

201: Behavioral Health

501: C-reactive protein

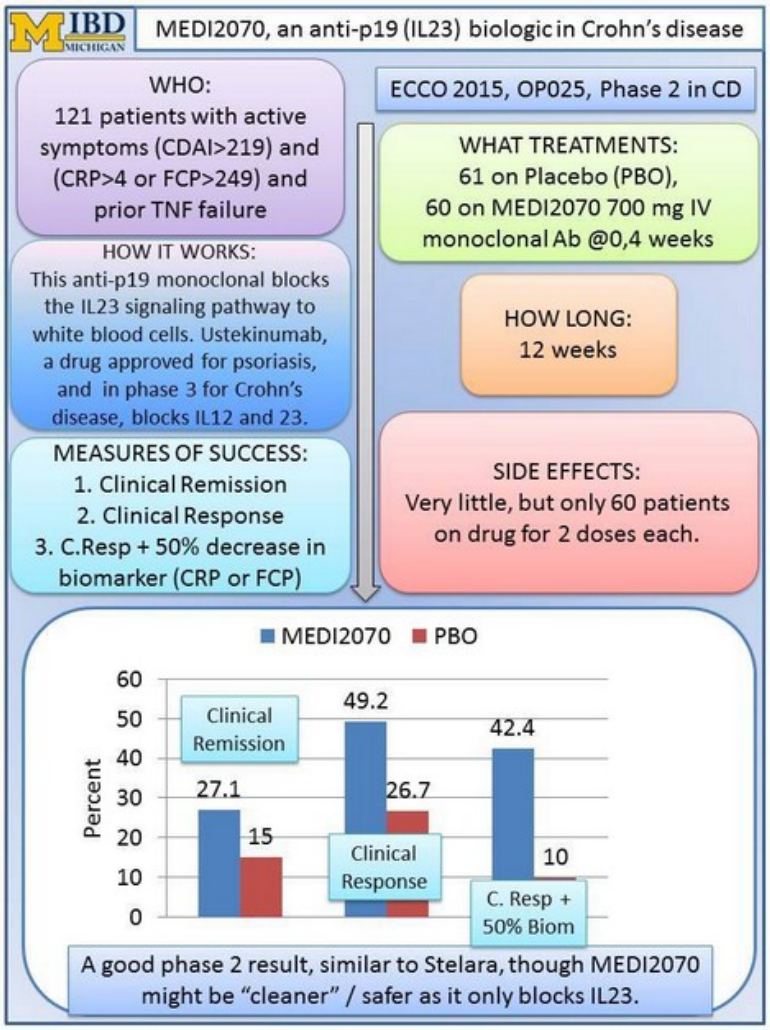
502: ESR

503: Fecal calprotectin

504: CBC - Part I

505: CBC - Part II

To help you and your family better understand Crohn's disease and ulcerative colitis, the University of Michigan Crohn's and Colitis Program has created a number of short, educational videos called IBD School Series. Our goals are for you to understand your disease, understand your choices of tests and treatments, and make more informed decisions that will improve your health and well- being. The videos can be found at: **www.med.umich.edu/ibd**



What's in the Pipeline for IBD Therapies?

There are many new therapies currently in clinical trials for both Crohn's disease and ulcerative colitis. Pictured here is just one example of a successful phase 2 Crohn's trial with a new biologic therapy known as MEDI2070 from AstraZeneca pharmaceuticals and MedImmune, Inc. The University of Michigan was one of 50 sites in the world to conduct this trial.

This biologic binds the p19 protein, which is part of the IL23 receptor in the lining of the gut. MEDI2070 is designed to be more specific than other biologics in its class, such as ustekinumab (Stelara), which acts on both IL12 and IL23 receptors. Compared to placebo, patients on MEDI2070 had higher rates of clinical response and clinical remission after just 12 weeks of being on the study medication.

Ongoing IBD Clinical Studies

BERGAMOT for Crohn's

Drug: Etrolizumab, injection under the skin

This is a phase 3 study for patients with moderate to severely active Crohn's disease to evaluate the safety and effectiveness of Etrolizumab, a Beta 7 anti-integrin that acts on the lining of the gut to block white blood cell trafficking. If enrolled in the study, patients have the ability to receive free Etrolizumab for up to 3 years.

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.

Abbvie M-14 for Crohn's and UC

Drug: Humira, injection under the skin

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.

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.

Rifaximin for Crohn's

Drug: Rifaximin, taken as a pill

This is a one year study to assess the efficacy and safety of twice daily oral rifaximin delayed-release (DR) tablets in subjects with active moderate Crohn's disease. Patients will be randomized in a 1:1 ratio at week 0 to either rifaximin DR tablets 800 mg twice a day or placebo. The treatment period will last up to 52 weeks and will assess clinical remission and endoscopic response.

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. We will also provide subjects with a Fitbit device to wear daily in order to track daily sleep, steps, and heart rate.

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!

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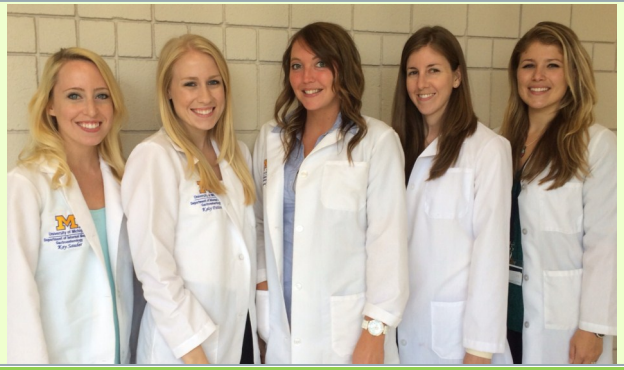
734-615-4843

734-647-2564



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