



**TOGETHER, WE
CAN CHANGE THE
FUTURE OF IBD**

Thank You UM Research Participants!

We would like to give a special thank you to all of the patients who have given their time and participated in a clinical trial here at the University. Performing clinical trials is the only way that we are able to find new medications that could be beneficial for patients with Inflammatory Bowel Disease, such as Crohn's disease and ulcerative colitis. Recently, the FDA has approved a medication for Crohn's disease and ulcerative colitis from one of our clinical trials. This medication is known as Entyvio and will be available for patients this summer. This important step forward in the treatment options for IBD could not have been possible without our dedicated and truly altruistic research participants. Because of them, patients with Crohn's and ulcerative colitis around the nation will have the opportunity to benefit from this medication. With your help, we will continue to find new medications that will help improve the lives of patients with IBD.

IBD News You Can Use

Why do people with IBD get low iron?

People with IBD are more likely to have anemia, which is a term used to describe a low red blood cell count. Red blood cells are very important, as they help carry oxygen all over your body. In IBD patients, anemia often results from the poor absorption of vitamins and minerals that can occur from inflammation of the intestines or diarrhea. When the intestines can't absorb enough nutrients, it inhibits the body's ability to make new red blood cells. Another cause of anemia in IBD is continual blood loss, even in small amounts.

The most common types of anemia in IBD patients are Iron deficiency anemia, vitamin deficiency anemia, and anemia due to a chronic condition. Iron deficiency anemia occurs when the body doesn't have enough iron which is used to make hemoglobin, a part of the red blood cell. This may be due to absorption problems, not getting enough iron in your food, or bleeding inside your body. Vitamin deficiency anemia is caused by poor absorption of folic acid and Vitamin B12 caused by IBD or not consuming enough of these in your diet. Along with iron, these nutrients are essential to producing red blood cells. Anemia due to a chronic condition such as IBD can happen when a chronic disease interferes with the production of red blood cells. It often improves as symptoms of the disease improve.

Symptoms of anemia include fatigue, dizziness or lightheadedness, irritability, numbness or coldness in hands or feet, pale skin, shortness of breath, rapid heartbeat with mild exertion, weakness, and in rare cases, chest pain. Anemia often comes on gradually, therefore isn't noticeable right away. A simple blood test is all you need to quickly diagnose. Treatment for anemia can take some time especially when using iron or other supplements to help increase the production of red blood cells. If you are at risk for developing anemia or are experiencing any of the symptoms above, talk to your doctor about getting tested.





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VISIT OUR WEBSITE:

U-M Inflammatory Bowel
Disease Program

www.med.umich.edu/IBD

Ongoing IBD Clinical Studies

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. The study is 9 weeks long, with an 80% chance of receiving active drug. Patients who complete the first 9 weeks may be eligible to enter the maintenance study of 52 weeks, and/or the open-label extension study and receive active drug for 3 years.

Title: HICKORY for UC Drug: Etrolizumab, SC 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 $\beta 7$ therapy that regulates white blood cell trafficking in the lining of the intestines. The study begins with a 14-week double-blind induction phase where patients will be randomized to 105mg Etrolizumab or placebo. There is a 80% of receiving active medication. After week 14, patients will be eligible to enter either the maintenance phase or open label phase depending on response to induction therapy.

Title: Tofa for Crohn's Drug: Tofacitinib (CP-690,550) – oral medication

This is a phase 2b study of subjects with moderately to severely active Crohn's disease. The medicine is the same JAK inhibitor from the OCTAVE trial for UC. The study lasts 8 weeks. Those who complete the treatment period and meet the definition of clinical response or clinical remission will be eligible to enter a placebo-controlled maintenance study of 26 weeks and then the open-label extension study, meaning there is no placebo and you are guaranteed active drug.

Title: TRAFFIC-CD Drug: AMG 181, SC injection (under the skin)

This is a phase 2 study to evaluate the efficacy of AMG 181 compared with placebo in patients with moderate to severe Crohn's disease who have never tried an anti-TNF medication. AMG 181 is a fully human monoclonal immunoglobulin IgG2 antibody that specifically recognizes the human $\alpha 4\beta 7$ integrin heterodimer and blocks MAdCAM-1. This mechanism of action of AMG 181 reduces pathological bowel inflammation. Subjects will be randomized to one of 4 groups, placebo or AMG 181 21 mg, 70 mg, or 210 mg. There is a 1/3 chance of receiving placebo in the double blind study. At the end of the double-blind period (week 24), subjects will enter a 108-week open-label period and be given active AMG 181 every 3 months.

Title: GEM Project (observational study)

We are conducting this observational study to find out more about the genetic, environmental, and microbial aspects of Crohn's Disease. Recent studies have revealed that a small percentage of Crohn's disease runs in families. However, it is still a mystery why some relatives develop Crohn's and others do not. **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 two visits 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 reimbursed \$20 after the two visits are completed to thank you for your participation.



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