

IBD Patient News



Summer 2016

U-M Division of Gastroenterology

What is a Clinical Trial?

For those who have never been involved in research studies, the words “clinical trial” may be a little bit scary. Often patients don’t realize exactly what a clinical trial entails and all the benefits they have to offer. The Inflammatory Bowel Disease research team here at UofM, along with many other divisions of medicine, dedicates a large part of their research to therapeutic drug trials for Crohn’s disease and ulcerative colitis. These trials are an opportunity for patients with IBD to try new therapies that they would not normally have access to otherwise.

A typical therapeutic clinical trial consists of an induction phase, aimed to induce remission and a maintenance phase aimed to maintain remission. In most trials, patients will have a chance of receiving placebo (inactive medication) during the induction phase in order to prevent any bias. Patients will often experience a placebo-effect, or the belief that a treatment is working when in reality there is no clinical sign of disease improvement. Once patients reach the maintenance phase of the study, there is typically no placebo involved anymore and everyone is given active medication for anywhere from 2-4 or more years depending on the trial. All patients on study receive the study medication at no cost to them and often receive a stipend at each visit to reimburse for travel and time lost from work.

TAKE STEPS FOR CROHN’S & COLITIS

Take Steps Metro Detroit

June 18, 2016
Meininger Park, Royal Oak
9:00 a.m. Registration Opens
10:30 a.m. Walk Begins

Take Steps Northwest Ohio

September 24, 2016
Toledo Zoo
8:30 a.m. Registration Opens
9:30 a.m. Walk Begins

Take Steps Lansing

October 1, 2016
Hawk Island
3:00 p.m. Registration Opens
4:30 p.m. Walk Begins

Take Steps Ann Arbor

October 8, 2016
Gallup Park
10:00 a.m. Registration Opens
11:30 a.m. Walk Begins

For more information or to register visit

www.cctakesteps.org

**Patient Education
on the Road**

**Reserve your
spot today!**

August 11, 2016 - Toledo, OH

Contact Kay Sauder for a reservation or to get more
information on this upcoming event.

ksauder@med.umich.edu or 734-647-2564

Currently Enrolling IBD Clinical Studies

ETROLIZUMAB

HICKORY

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 $\beta 7$ therapy that regulates white blood cell trafficking in the lining of the intestines.

BERGAMOT

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.

GILEAD

Drug: GS-5745, injection under the skin

This is a phase 2 study for patients with moderate to severely active **Crohn's and ulcerative colitis** to evaluate the safety and effectiveness of GS-5745, a new biologic medication targeting MMP9.

VERSIFY

Drug: vedolizumab (Entyvio), infusion

This is a phase 4 study for patients with moderate to severely active **Crohn's disease**. Patients receive medication for 26 weeks.

UNIFI

Drug: ustekinumab (Stelara), injection under the skin

This is a phase 3 study for patients with moderate to severe active **ulcerative colitis**. The total time in the study could be up to approximately 220 weeks (4.25 years). If you qualify, you will receive study-related medications and physical exams at no charge to you. Participation will require regular monthly visits for the duration of the study.

OZANIMOD

Drug: RPC01, oral medication

There are two studies available. One for patients with moderate to severe active ulcerative colitis and another for those with Crohn's disease

The UC study is a two part study where those who qualify to participate will receive investigational medication during Part 1 of the study which lasts for 10 weeks. Patients who respond to the treatment at the end of 10 weeks will enter Part 2 of the study, which may continue for an additional 42 weeks. There is also an extension to this study which will go until 2020.

The Crohn's study is a phase 2 that has no placebo arm. There is a 12 week induction period and for patients who are responding they can continue into the 100 week maintenance portion.

LUX-MEDI2070

Drug: MEDI2070, injection under the skin

This is a phase 2 study for patients with moderate to severely active **Crohn's disease** to evaluate the safety and effectiveness of a new biologic medication targeting interleukin-23.

SASA SWITCH STUDY

This is a study aimed to switch patients with **ulcerative colitis** from an expensive 5-ASA to the more cost efficient sulfasalazine. We will work closely with patients to ensure proper dosing of sulfasalazine and monitor disease symptoms.

MONGERSEN UC

Drug: Mongersen (antisense to SMAD7)

A Phase 2, Open-label, Multicenter Study to Explore the Efficacy and Safety of Mongersen (GED-0301) in Subjects with Active Ulcerative Colitis.

Serene—M14

Drug: adalimumab (Humira)

This is a Phase 3 study for the purpose of evaluating the effectiveness and safety of two different adalimumab dosing regimens and to assess the pharmacokinetics of adalimumab following subcutaneous administration in subjects who have moderately to severely active Crohn's disease and evidence of mucosal ulceration.

Celeste—M13

Drug: ABT-494

This is a Phase 2 study to determine the efficacy and safety of multiple doses of ABT-494 versus placebo and to assess the pharmacokinetics of ABT-494 following oral administration in subjects with moderately to severely active Crohn's disease with a history of inadequate response to or intolerance to anti-TNF therapy.

Observational Study Opportunities

GEM Project

Our goal for this study is to follow healthy brothers, sisters and children of patients with Crohn's disease to try to 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 questionnaire's and give 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.



Upcoming Clinical Studies

ELI LILLY

Drug: LY3074828 (anti-IL23)

A Phase 2, Multicenter, Randomized, Double-Blind, Parallel, Placebo-Controlled Study of **LY3074828** in Subjects With Moderate to Severe Ulcerative Colitis.

PIONEER

Drug: CROWN

A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Effectiveness of a Nutritional Intervention in Improving the Intestinal Mucosal Health Status in Subjects with Crohn's Disease (CD) Receiving Induction Anti-TNF Therapy PIONEER-CD.



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Contact the UM IBD Clinical Trials Team!
email: higginsSCTeam@umich.edu or call 734-647-4548