IBD Patient News

University of Michigan Health System

February 2014 **U-M Division of Gastroenterology**

What is a Clinical Trial?

For those who have never participated in research, the words "clinical trial" may be a little bit scary. Often patients don't realize exactly what is involved in a clinical trial, and more importantly all the benefits they have to offer. The Inflammatory Bowel Disease research team here at UofM 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 medications that they would not otherwise have access to.

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 are randomly assigned to active medication or placebo (inactive medication) during the induction phase. While often as few as one in five patients are assigned to placebo, this is important to prevent possible bias since often patients experience a placebo-effect, or the belief that a treatment is working even if there is no disease improvement. Once patients reach the maintenance phase of the study, there is typically no placebo involved and everyone is given active medication for anywhere from 2 to 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.

When considering a clinical trial, it is important that you consult with your UM GI physician as well as the IBD study coordinator team. The study coordinators will work with your physician to determine the best study for you. For information on our current clinical trials, please see the reverse side of this newsletter.

IBD News You Can Use

Risk of Low Vitamin D in Patients With IBD

Recent studies have shown that patients with Inflammatory Bowel Disease are at greater risk for having low vitamin D levels. This can lead to osteoporosis, osteopenia and an overall higher rate of abnormal bone density. Several factors contribute to low Vitamin D levels including Crohn's disease of the small bowel, steroid use, and simply living in northern, colder states.

Vitamin D and calcium supplements are highly recommended for patients with IBD. As the temperatures warm up, 15-20 minutes per day outside to absorb some sun rays could also help boost your levels dramatically. Aside from over the counter vitamin supplements and natural sunlight, there are also ways to add vitamin D to your diet by eating fatty fish, canned tuna, mushrooms, orange juice, beef liver and certain cereals such as Cheerios. For more information please feel free to contact your health provider.

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TO SPEAK TO A NURSE:

734-936-0501

VISIT OUR WEBSITE:

U-M Inflammatory Bowel Disease Program

www.med.umich.edu/IBD

Ongoing IBD Clinical Studies

Title: TURANDOT for UC

Drug: anti-MadCAM-1, SC injection (under the skin)

This new subcutaneous biologic blocks the ability of blood vessels in the gut to attract white blood cells. This is the complement of anti-integrin therapies like vedolizumab, with injections every 4 weeks. Patients are randomized to 1 of 4 doses of active drug or placebo (4:1) for 12 weeks, followed by an open label treatment for up to 52 weeks.

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: TRAFFIC-CD

Drub: AMG 181, SC injection (under the skin)

This is a phase 2 placebo-controlled, multiple dose study to evaluate the efficacy of AMG 181 compared with placebo as measured by the proportion of subjects in remission (CDAI score < 150) at week 8. AMG 181 is a fully human monoclonal immunoglobulin IgG2 antibody that specifically recognizes the human α4β7 integrin heterodimer. AMG 181 binds α4β7 with high affinity and blocks its interaction with MAdCAM-1. This mechanism of action of AMG 181 reduces pathological bowel inflammation. Subjects will be randomized in a 2:1:2:1 ratio to receive placebo or AMG 181 21 mg, 70 mg, or 210 mg. At the end of the double-blind period (week 24), subjects will enter a 108-week open-label period during which all subjects will receive open-label 210 mg AMG 181 every 3 months.

Title: UNITI 2 for Crohn's Disease

Drug: Ustekinumab (Stelara®) IV infusion and SC injection (under the skin)

This phase 3 study is looking at the efficacy of Ustekinumab (Stelara®) in patients with moderate to severe Crohn's disease who have never taken an anti-TNF therapy (Remicade, Humira, Cimzia) or had to discontinue for a reason other than failure (loss of insurance). This drug blocks activity of IL 12/23 and is currently approved in psoriasis and psoriatic arthritis. The study consists of an 8 week placebo controlled induction followed by a maintenance treatment phase that will continue for up to 4 years.

Title: GEM Project

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.

Contact the UMHS Clinical Trial Team:

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