IBD Patient News

University of Michigan Health System

Summer 2013 U-M Division of Gastroenterology

Why Not to Skip a Dose of Your Biologic Medication

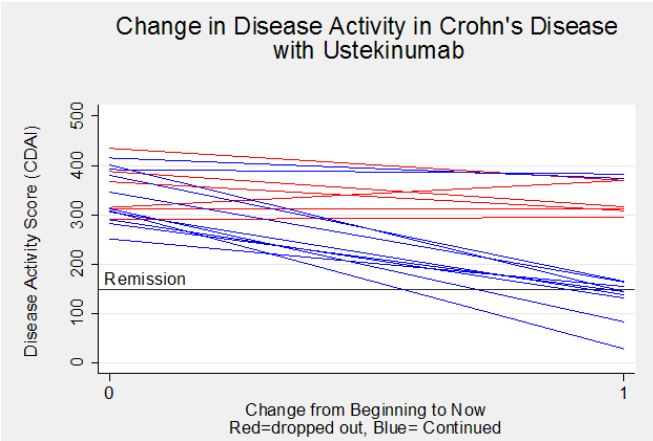
Many patients who start on a biologic medication (like Remicade, Humira, or Cimzia) improve dramatically, and once the feel better, wonder if they can stop taking the drug, or just skip a dose or two. This might be for convenience (it can be hard to make it to Remicade appointments, or get Humira refilled on time). It could be for cost reasons, as these are expensive medications. Or sometimes it is because patients are worried about side effects of the medication.

Unfortunately, starting and stopping biologic medications can be a real problem. When your body sees very low levels of the drug, it is recognized as a foreign protein, and antibodies against the drug are made. These antibodies lead to more rapid clearance of the drug, so that there is less in your body after each dose, and the drug works less and less. In effect, stopping and starting a biologic is a lot like immunizing yourself against the drug. Therefore, it is better to stop the drug completely, or never start it at all, than to use it intermittently

If you are thinking about stopping a biologic medication, please discuss your plans with your physician. There may be information we can give you that might help. If cost is an issue, go to the IBD website at www.med.umich.edu/ibd and click on the link for Patient Assistance Programs. Each company has programs to reduce the cost or even give you medication for free.

Results from the UNITI 1 Stelara® Crohn's Disease Trial

The UNITI program for Crohn's Disease is being conducted worldwide to test the efficacy of the drug Ustekinumab (Stelara®). Each study participant receives a baseline measurement of their disease activity, known as a CDAI score. Additionally, throughout the study this is re-calculated to see if the drug is helping the symptoms of Crohn's. Patients are considered to be moderately to severely active with a score between 220 and 450, and be in remission (without significant symptoms) when their CDAI score reaches 150 points or lower.



Each line on this graph to the right represents a study participant here at U of M. The blue lines indicate patients who are still participating in the study. The red lines represents discontinued patients. Zero represents the baseline score, one represents their most recent score.

As you can see, many of the patients that began with a high CDAI score experienced a significant reduction in their symptom score. A number of patients even achieved remission. Obviously not all reported an improvement, although that is the ultimate goal of participation.

University of Michigan Health System

TO SPEAK TO A NURSE:

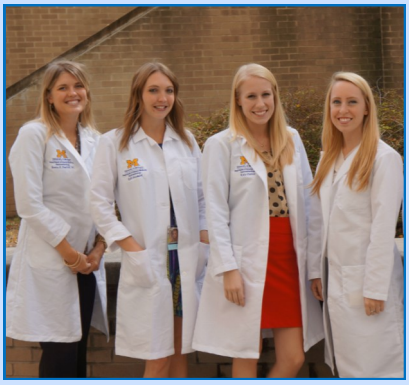
734-936-0501

VISIT OUR WEBSITE:

U-M Inflammatory Bowel Disease Program
www.med.umich.edu/IBD

Interested in a trial?

CONTACT the UMHS Clinical Trial Team
HigginsSCTeam@umich.edu
734-647-2564 or
734-615-4843



Ongoing IBD Clinical Studies

See a few short descriptions of our trials for Crohn's disease and ulcerative colitis:

Title: TURANDOT for UC
Drug: anti-MadCAM-1
Description: 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 one 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
Description: This is a Phase 3 study in 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 and responders can enter a placebo-controlled maintenance study of 52 weeks. Subjects who did not benefit are eligible to enter an open-label extension study and receive active drug for 3 years.

Title: PEBBLE for Crohn's Disease
Drug: anti-IL23
Description: This phase 2 study of a biologic randomizes patients 1:1 to biologic or placebo. The IL-23 blockade is expected to work like ustekinumab (Stelara), but may have a more direct benefit. After 12 weeks, all patients can roll over to open-label maintenance therapy with active drug. This open-label extension can provide free drug for patients for up to 2 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.

Study Participant Testimonial

"Having spent the last year or so in a study related to my Crohn's disease, I would tell you that if you have the opportunity to consider a clinical trial, you should seriously consider it. In my case, a few important benefits have occurred… First, I feel better overall and have experienced a reduction in symptoms with the disease, and Secondly, the trial has challenged me to be more engaged with my health and stay on top of concerns or triggers that might otherwise go unnoticed as a busy working mom with two small children. **…I am very grateful for the opportunity and fully believe that the attention I pay now to my health and stress levels coupled with the drug, have given me more energy, better health and less anxiety. "** *- Subject KJW, UNITI Trial*