



Flu Season is On the Way!

It is that time of year again; flu season is upon us. The American Gastroenterological Association, the Crohn's and Colitis Foundation of America, and the Centers for Medicare and Medicaid Services have all agreed that it is important for patients with inflammatory bowel disease to get flu shots every year. Last year we had one patient spend more than a week on a ventilator in an intensive care unit with flu, and we have already had one IBD patient hospitalized with flu this year.

Giving patients the flu vaccine is considered a requirement for high-quality care of IBD patients, so we are required to order the flu shot for every IBD patient. We would like to get everyone vaccinated before December 1st, and hopefully keep everyone out of the intensive care unit this year. Important things you should know about the flu shot:

- ◆ IBD patients should get the shot, not the nasal spray (the nasal spray is a LIVE vaccine)
- ◆ This year's vaccine covers four types of flu, more than the usual
- ◆ If you have an egg allergy, there is a new egg-free vaccine called FluBlok
- ◆ If you choose to refuse the flu shot, we must document this in your medical record
- ◆ If you have had the flu shot somewhere else already, tell us when and where so that we can document this

IBD News You Can Use

High Altitudes May Increase the Risk of IBD Flares

Researchers have found that flying or traveling to high altitude locations seems to increase the risk for flares in people with inflammatory bowel disease (IBD). The initial idea for the study was generated by reports from skiers and mountaineers with IBD who complained of flares within a week of being at higher elevations. It is known that being in a state of hypoxia, when the body is deprived of adequate oxygen supply (i.e. at high altitudes), can result in inflammation in the gastrointestinal tract. However, the impact that hypoxia has on IBD is not well understood.

The goal of this study was to evaluate whether flights and/or journeys to regions lying at an altitude of greater than 2000 meters above sea level were associated with flare-ups within 4 weeks of the trip. IBD patients with at least one flare-up during a 12 month observation period were compared to group of patients in remission. A total of 103 patients participated, 43 with Crohn's disease, 60 with ulcerative colitis, and 52 patients with flare-ups were matched with 51 patients in remission. All patients completed questionnaires about their travel and habits during the observation period.

Overall, patients with flares reported significantly more flight and/or traveling to places 2000 meters or more above sea level than patients in remission (40.4% vs. 15.7%). For Crohn's disease, there was a correlation between flares and high-altitude journeys (i.e. skiing or mountain climbing at high altitudes) in patients with flares, compared to those in remission. For ulcerative colitis, there was trend toward more frequent flights and high-altitude journeys in patients with flares.

It can be concluded that journeys to high altitude regions and/or flights are risk factors for IBD flare-ups within 4 weeks of travel. However, according to researchers it is too early to tell patients to avoid high altitudes until future research is done to closely examine the effects of hypoxia on inducing IBD flares.





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TO SPEAK TO A NURSE:

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VISIT OUR WEBSITE:

U-M Inflammatory Bowel Disease Program

www.med.umich.edu/IBD

Ongoing IBD Clinical Studies

Short descriptions of our trials for Crohn's disease and ulcerative colitis:

Title: TURANDOT for UC

Drug: anti-MadCAM-1

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

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

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: UNITI 2 for Crohn's Disease

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

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
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