

Clinical Trial Seeks Eligible Patients With Ulcerative Colitis

(NAPS)—Only 23, Amy Gorelow already knows more than most people about sensitive issues. Along with her theater company, she conducts workshops to help students better deal with sensitive issues. But her most sensitive role is off-stage. She has signed up to be part of a clinical study so that others with a painful and embarrassing disease can have a better life.

Gorelow has ulcerative colitis, a chronic disease associated with inflammation of the gastrointestinal tract and characterized by frequent diarrhea, discomfort and a persistent urge to go to the bathroom. Ulcerative colitis affects about half a million Americans, many of them initially diagnosed in their 20s and 30s.

Ulcerative colitis (UC) also increases the risk of developing colon cancer, and is often one of the biggest concerns of people with the disease. That's one reason Gorelow entered the trial.

Gorelow relayed, "Having a disease like this makes acting very challenging. I had to move in with my mother for several weeks at a time because of the disease. I wish I could live my life without worrying about when my next flare-up will be."

The trial, involving over 600 patients nationwide, will be testing the safety and efficacy of a higher dose and investigational formulation of Asacol® (mesalamine delayed release tablets). Asacol is an anti-inflammatory drug. Approved in the U.S. since 1992,



Asacol is currently indicated for the treatment of mildly to moderately active ulcerative colitis and for the maintenance of remission.

The side effects of UC therapy are a major concern for patients and one reason that as many as 41 percent of the 500,000 UC patients in the U.S. don't take their medication as directed. Because UC is a chronic illness, it must be treated consistently to prevent "flare-ups" and to keep the disease from worsening. As the disease worsens, stronger medications like steroids, which have many potentially serious long-term side effects such as osteoporosis, ulcers, cataracts, and skin disorders, must be used.

Dr. Stephen Hanauer of the University of Chicago, one of the nation's foremost IBD experts and the lead investigator for the nationwide UC trial, indicated that although there are no guarantees, the information gained from the clinical trials could help both patients and physicians in the future.

"Although this is an investigational treatment for UC and the outcomes are not yet known, the study will help determine if increased doses of Asacol® could potentially improve a patient's quality of life and give physicians a much-needed treatment option that may have fewer side effects."

Trial Participants Needed

Approximately 100 trial sites nationwide are opening their doors to men and women like Gorelow, aged 18 to 75, who have been diagnosed with mildly to moderately active ulcerative colitis. Enrollees in the study receive free study-related medications and physical exams during the seven-week study. Patients can call the trial hotline at 1-800-214-1535 to find the trial site nearest them, or by logging on to www.living-better.com.

"It is important that people with IBD know clinical trials like this are ongoing," said Dr. William Sandborn, head of the Clinical Research Alliance for the Crohn's & Colitis Foundation of America (CCFA). CCFA has dedicated a portion of its Web site, <http://www.ccfa.org>, to help IBD patients find clinical trials for which they may qualify. "Trial participants should know that their participation may help others suffering from this disease have quicker access to new treatment options."

More information about IBD and its treatment is also available through the CCFA Web site at www.ccfa.org.