

Low-dose Naltrexone for Crohn's Disease

In 1982, Dr. Ian Zagon and Dr. Patricia McLaughlin at Hershey Medical Center, Penn State University College of Medicine, discovered that naltrexone - approved by the FDA in 1984 for treating substance abuse - also triggers the production of higher levels of naturally occurring opioids (also known as endorphins) when used at a fraction of the usual dose. This prompted Dr. Zagon and his team to research the application of naltrexone in treating various other conditions.

In 2004, Moshe Rogosnitzky, director of research at MedInsight Research Institute, presented evidence to Dr. Zagon that increased endorphin levels could have a beneficial effect in treating Crohn's disease. As a result of this information, Dr. Zagon and Dr. Jill Smith, Professor of Gastroenterology at Hershey Medical Center, launched a preliminary clinical trial using a low dose of readily available naltrexone.

Backed by seed funding from Penn State University, the results of the clinical trial demonstrated the treatment to be remarkably effective. Eighty- nine percent of treated patients experienced significant improvement in their symptoms, and two-thirds experienced remission.

“This is a novel, yet effective, approach to treating a common disease,” says Dr. Smith. A follow-up controlled trial, sponsored by the Broad Medical Foundation and the National Institutes of Health, has been launched by Drs. Smith and Zagon to confirm the results of the first study.

Dr. Zagon, study co-author, is also encouraged by the findings. “I am delighted to see this study published,” says Dr. Zagon. “Although it is a preliminary investigation, and its findings need to be verified by controlled studies, it points to the efficacy of low-dose naltrexone in treating patients with Crohn's, a devastating and debilitating disease.”

Co-author Moshe Rogosnitzky agrees. “Once the results of this study are confirmed,” he says, “we will have perhaps the safest and so-far most- effective overall treatment for Crohn’s disease.”

Ironically, the low cost of LDN treatment could prove to be a disadvantage. Few drug companies have the incentive to invest the funds necessary to obtain FDA approval for this new indication.

Nevertheless, Dr. Smith remains confident. “We have already been approached by biotech companies with an interest in licensing this therapy,” she says. “Because naltrexone is already approved for other uses, it should be a relatively inexpensive process to obtain FDA approval for its use in Crohn’s disease.”