A recent Norwegian study generated a burst of media attention over the improvement reported by a small group of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) patients treated with a drug usually used for cancer and autoimmune disease. Researchers at the Haukelund Hospital in Norway discovered, by chance, that a patient, with ME/CFS and lymphoma, experienced major relief from ME/CFS symptoms while receiving rituximab for lymphoma. This preliminary finding led to a double-blind, placebo-controlled phase II study of 30 patients with ME/CFS who were given either rituximab or saline infusions. Patients reported their ME/CFS symptoms had either completely resolved or that many symptoms had improved considerably. However, the positive responses to the rituximab were not immediate (i.e., there was a delayed-response pattern noted) and these tapered off as the effects of the drug wore off. Links are provided at the end of this article, for sites with more details and reviews on the clinical trial as well as the drug.

Positive press for ME/CFS is always welcome, but the media has a tendency to sensationalize news and often, the information reported is incomplete or incorrect. It is too premature to publicize ME/CFS as a "treatable" autoimmune disease, as done by some of the online news sites. The *Haukelund Study* was able to confirm immune system involvement in ME/CFS and demonstrate the impact of B-cell depletion in ME/CFS. The study findings also help to point to a new direction for future treatment research, but this drug is not currently approved for ME/CFS. Furthermore, it yet remains to be seen if clinical trials for rituximab in ME/CFS will be conducted by the pharmaceutical companies that manufacture it in the U.S. Dr. David Bell, a researcher/clinician who has worked with ME/CFS for 25 years, seemed very enthusiastic about the rituximab trial during a Norwegian TV interview. Dr. Bell remarked how he has not seen anything like this to-date which could provide this level of recovery in ME/CFS patients and he also felt this study raises the possibility of looking at ME/CFS as an autoimmune illness.

Though no serious adverse reactions were reported in the *Haukelund Study*, it is important to recognize rituximab as a very potent treatment. Rituximab belongs to a class of drugs called monoclonal antibodies and in very general terms, it works by recognizing and binding to a specific protein (i.e., CD20 which is the cell surface protein exclusively expressed on B cells) and depleting B-cells. B-cells are both good and bad, as they provide immunity against diseases and pathogens but they can also attack one's own tissues. Rituximab eliminates all mature B-cells, which in turn, can leave a patient vulnerable to dormant viruses and/or unable to fight off infections. It is administered as an intravenous infusion and usually done in a hospital setting. Currently, rituximab (i.e., co-marketed as Rituxan by Genentech /Biogen Idec in the U.S.) is approved by the U.S. Food and Drug Administration (FDA) for treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, and incurable, inflammatory disease of blood vessels (i.e., Wegener's granulomatosis and microscopic polyangiitis). It is a powerful medication that can cause significant side effects, including life-threatening reactions and/or complications. It is not recommended for use in patients with severe, active infections because it can worsen these and/or trigger reactivation or exacerbation of viral infections, according to the Genentech/ Biogen Idec patient information website.

Most patients with ME/CFS tend to be hypersensitive to many medications and it is likely that some might not be able to tolerate something like rituximab. As with any treatment, the benefits will need to be carefully weighed against the potential risks-rituximab comes with a *black box warning* (i.e., deaths within 24 hrs of infusion have occurred and approximately 80% of fatal infusion reactions occurred in association with the first infusion) and thus, treatment requires extreme caution and close monitoring. A common recommendation for ME/CFS is to keep a two-year "observe only" rule (i.e., pay attention to the drug's performance (track record) for a couple of years before initiating treatment). Until a larger number of patients can be studied on this medication, it is not possible to conclude if rituximab will become a viable treatment option for ME/CFS.

Additional information - 2011:

Free access to the research article, Benefit from B-Lymphocyte Depletion Using the Anti-CD20 Antibody Rituximab in Chronic Fatigue Syndrome. A Double-Blind and Placebo-Controlled Study published on October 19, 2011 by PLoS One (an international, peer-reviewed, open-access, online publication source).

Rituxan (rituximab) patient information site , prepared by Genentech/ Biogen Idec.

A constructive review of rituximab (as a series of questions and answers) compiled by the ME Association in the UK and posted at Prohealth: Rituximab Clinical Trial: Questions and Answers (revised Nov 2, 2011) .

Additional information - 2012:

"VIDEO: MECFS Alert on new California ME/CFS clinic, managing 1,000 patients & running rituximab trial" (ProHealth's ME/CFS Research and News, ProHealth.com - 2012) A 6 ½ minute (YouTube) interview with Llewellyn King and Andreas Kogelnik, MD, PhD, director of the newly founded Open Medicine Institute in Mountain View, CA. Some of the projects/research planned by the institute will be a rituximab pilot and multi-site Ampligen trial which will involve a network of key ME/CFS specialists.

For Those Wondering About Progress on Rituximab Trials for Chronic Fatigue Syndrome (ProHealth.com, March 29, 2012)