



Intravenous Immunoglobulin (IVIG) Does NOT Treat PPS

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Let me tell you an unbelievable story. I mean literally unbelievable.

Sweden, 2004 – “Xepol” was described in Karolinska Institute press release headlined “Promising anti-inflammatory treatment for post-polio syndrome.” Sixteen polio survivors with muscle weakness were treated with Xepol, which is intravenous immunoglobulin (IVIG), a standard treatment for inflammatory diseases. “Most patients reported improvements in their physical status. However, the value of this is unclear, since this first study did not include a placebo group.” Value unclear without a placebo group? No kidding.

Sweden, 2006- A Xepol study was finally published in a medical journal. IVIG was given to 73 polio survivors and placebo to 69, then given again in three months. There was no improvement in fatigue, general muscle strength, pain, walking speed, balance or sleep quality. There were only four benefits: A “selected study muscle” increased in strength by 2%, a greater decrease in “significant pain,” a 10% increase in reported “vitality” and a 19% increase in physical activity compared to the placebo group.

Did Xepol help polio survivors? First, the placebo group had worse symptoms than the Xepol group to begin with, making it harder for them to show any benefit. Second, this was not a placebo-controlled study. IVIG subjects had noticeable and unpleasant side-effects as compared to the placebo group: 30% reported itching and rash with IV, 29% reported headache, 19% reported nausea and 10% reported feeling cold. Since as many as 30% of the Xepol subjects could have figured out that they were getting IVIG, any improvements could be due to the placebo effect.

Sweden, 2008 - A press release trumpeted, “PHARMALINK REPORTS POSITIVE RESULTS FOR XEPOL,” “effective and well tolerated” in the same subjects reported in the 2006 journal article, but who were now one year post treatment. Pain, walking ability and self-report of health “all showed significant and clinically meaningful results,” the release hailed. Said Pharmalink’s managing director, “We are very excited about this data as patients in the treated group have experienced a reduction in disease symptoms after just 12 months.”

Whoa! First, the published six-month study showed no significant improvement in pain or walking ability. Second, since the new twelvemonth data hasn’t been published, so we can’t know if any of the new results produce a “significant and clinically meaningful reduction in disease symptoms.” Third, even the release said that the placebo group also reported a decrease in pain and improved walking after 12 months. Finally, the company was “very excited” because polio survivors had a reduction in symptoms “just 12 months” after taking Xepol? “Just 12 months?” Can you imagine any drug company excitedly proclaiming, “NEW HEADACHE MEDICATION WORKS JUST 12 MONTHS AFTER TAKING THE PILL?”

North America, 2009 – I received e-mails from polio survivors in the US and Mexico. Doctors were making presentations about Xepol to post-polio support groups and then asking polio survivors for donations to perform studies using Xepol.

Sweden, 2010 – “Pharmalink AB, today announced agreement with Grifols for the acquisition of Xepol (R)...human immunoglobulin for the treatment of (PPS). This agreement marks a significant milestone in Pharmalink's corporate development. Grifols will develop the PPS product opportunity. In several clinical trials lead by a team of physicians at Karolinska Institutet, immunoglobulin has shown significant and clinically meaningful results in pain, walking ability and quality of life by down-regulating the inflammatory process in the nervous system of PPS patients.”

“Significant and clinically meaningful results in pain, walking ability and quality of life?” Not in the one published study. And, none of the studies, published or not, ever measured “down-regulating the inflammatory process.” What is “significant” is the “milestone in Pharmalink's corporate development,” having sold Xepol to a company with the cash to “develop the PPS product opportunity” without polio survivors having to fund it.

I've been around long enough to remember a 1995 NIH study that found that high doses of prednisone, the king of anti-inflammatory drugs, didn't decrease PPS symptoms but did cause horrible side effects. A 2007 Norwegian study found no change in polio survivors' “fatigue and muscle strength” three months after IVIG treatment.”

One post-polio boat sailed long ago: Inflammation does not cause PPS. That is unless you're a corporation that “publishes” research via “very excited” press releases and happens to have a “product opportunity” that may make you a buck... or 1,500 bucks, the cost of just one Xepol treatment.