

Etanercept - genetically engineered compound for back pain - falls short: study

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Despite the great promise that injecting a new type of anti-inflammatory pain medicine into the spine could relieve the severe leg and lower back pain of sciatica, a Johns Hopkins-led study has found that the current standard of care with steroid injections still does better.

Etanercept, sold by the brand-name Enbrel, is a genetically engineered small-protein drug known as a [tumor necrosis factor](#) inhibitor (TNF). Currently, it is used to treat [rheumatoid arthritis](#) and other autoimmune disorders in which the immune system attacks healthy tissue causing pain, swelling and damage. The drug blocks TNF, a naturally produced substance that causes inflammation.

Although steroids combat inflammation generally, TNF inhibitors specifically target the inflammatory molecules causing sciatica and other pain conditions, and keep them from binding to receptors in the [central nervous system](#), potentially preventing the pain altogether.

A team led by Steven P. Cohen, M.D., an associate professor of anesthesiology and [critical care medicine](#) at the Johns Hopkins University School of Medicine, conducted a blinded, placebo-controlled study, providing epidural injections of either 60 milligrams of a steroid, 4 milligrams of [etanercept](#), or 2 milliliters of saline to 84 adult patients with sciatica. One month after the second of two injections, the patients on steroids reported less pain and less disability than those in the other two groups. The study is published in the April 17 issue of the [Annals of Internal Medicine](#).

Cohen said studies with etanercept grew out of efforts to prevent or limit the pain that commonly comes from a herniated disc pressing on a [nerve root](#) in the lower back or neck. Steroids work, he said, but they are not without drawbacks, including mixed and only temporary results in relieving pain, and the potential for catastrophic complications. Pain experts have long been working to try to find an alternative treatment that is safe and reliable, he notes.

"People are desperate for a safer, more effective drug," Cohen says. "This new treatment shows a lot of promise, but at least in the doses we gave it - the dose known to be safe - steroids still work better. And in those lower doses, etanercept may not be the drug everyone's hoping it is. There's still a lot more work to be done."

Cohen says a study published last month found that patients who received more than twice as much etanercept as was used in his study felt better than those who got steroids one and two weeks after their injections, but not four weeks out. The dose of etanercept administered by Cohen's team - 4 milligrams - was deemed to be the optimum dose found to be both safe and effective in a pilot study done by Cohen and colleagues in patients and animals.

The idea behind administering an epidural injection for sciatica is to bathe the spinal nerve roots directly in a medication designed to reduce inflammation - and pain - in order to give the body time to heal itself, Cohen says. This allows for better relief at lower doses and, in turn, fewer side effects than when the medications are given by mouth or intravenously.

The new study found that more patients treated with epidural steroids (75 percent) reported 50 percent or greater leg pain relief and felt better overall after one month compared to those who received saline (50 percent) or etanercept (42 percent). On a pain scale of 0 to 10, with 10

denoting the worst pain, those who received steroids reported, at one month, an average pain score of 2.1 compared with 3.6 in the etanercept group and 3.8 in the group injected with saline. Those in the steroid group also reported lower levels of disability (21 percent) than those in the saline group (29 percent) or etanercept group (38 percent).

After six months, however, slightly more patients in the saline (40 percent) and etanercept (38 percent) groups had a positive outcome than those in the steroid group (29 percent).

"The effect of the steroids didn't last," Cohen says, "affirming the fact that steroids work, but not for very long."

Cohen says research now needs to be done to test the safety and effectiveness of higher doses of etanercept and other drugs that block the inflammatory molecules responsible for pain.

Provided by Johns Hopkins Medical Institutions

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