

Preliminary results for combined therapy show improvement in MS symptoms

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Combining the estrogen hormone estriol with Copaxone, a drug indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS), may improve symptoms in patients with the disorder, according to preliminary results from a clinical study of 158 patients with relapsing remitting multiple sclerosis (RRMS). The findings were presented today by Rhonda Voskuhl, M.D., from the University of California, Los Angeles, at the American Academy of Neurology Annual Meeting in Philadelphia. The study was funded by the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health; and the National Multiple Sclerosis Society.

"While these results are encouraging, the results of this Phase II study should be considered preliminary as a larger study would be needed to know whether benefits outweigh the risks for persons affected by MS. At present, we cannot recommend [estrogen](#) as part of standard therapy for MS. We encourage [patients](#) to talk with their doctors before making any changes to their treatment plans," said Walter Koroshetz, M.D., deputy director of NINDS.

MS is an autoimmune disorder in which immune cells break down myelin, a protective covering that wraps around nerve cells. Loss of myelin results in pain, movement and balance problems as well as changes in cognitive ability. RRMS is the most common form of the disorder. Patients with RRMS experience relapses, or flare-ups, of [neurological symptoms](#), followed by recovery periods during which the

symptoms improve.

Numerous laboratory studies have suggested that estrogen may have neuroprotective effects and may help decrease inflammation, which occurs in MS. In addition, it has been reported that MS patients experience improvement in symptoms during the phase of pregnancy when levels of estrogen increase. However, studies looking at the effects of [estrogen therapy](#) on women's health have shown mixed results. Estriol, the form of estrogen examined in this study, is only produced in the body during pregnancy.

In this two-year study, patients received Copaxone along with 8 milligrams per day of estriol or placebo pills. The primary goal of the trial was to determine if estriol helped decrease the number of relapses experienced by RRMS patients who were also taking Copaxone.

Researchers found that at 12 months, estrogen combination therapy was associated with a greater reduction in relapse rates compared to Copaxone and placebo. However, at 24 months, the difference between the treatment groups was not as great as it was at 12 months.

"The findings presented by Dr. Voskuhl suggest that there may be benefits to supplementing Copaxone therapy with estrogen. A longer study, with more patients, would be necessary to definitively validate these provocative, although early, findings," said Dr. Koroshetz.

More information: For more about MS, please visit:
www.ninds.nih.gov/disorders/multiple_sclerosis.htm

Provided by National Institutes of Health

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