National Multiple Sclerosis Society
733 Third Avenue
New York, New York 10017-3288
Tel +1 212.986.3240
Fax +1 212.986.7981
E-mail nat@nmss.org
nationalmssociety.org

RESEARCH/CLINICAL UPDATE

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MS Trial Alert:
Clinical Trial of Sex Hormone Estriol Recruiting Women with MS to Participate

In the first effort of its kind in MS, UCLA neurologist Dr. Rhonda Voskuhl is leading a team of investigators at seven medical centers to conduct a two-year, controlled clinical trial of a sex hormone added to standard therapy to treat MS. Investigators plan to administer either oral estriol along with Copaxone® (glatiramer acetate, Teva Pharmaceutical Industries Ltd.) or Copaxone plus inactive placebo to 130 women with relapsing-remitting MS. If successful, this clinical trial could lay the groundwork for a larger, definitive trial that could lead to a new treatment option for women with MS. Its results may also have implications for women with other autoimmune diseases, such as rheumatoid arthritis. Women with relapsing-remitting MS interested in the possibility of participating in the trial should consult with their physicians or contact one of the medical centers listed below.

This study, costing more than $5 million, is being funded by the National MS Society in partnership with the Society's Southern California chapter and the National Institute of Neurological Disorders and Stroke. Pipex Pharmaceuticals, Inc., has manufactured oral estriol tablets as well as matching placebos, and is providing them for this clinical study.

Stems from National MS Society's Gender Initiative

MS affects women two to three times as often as men. This and other gender differences became the topic of a special, five-year research initiative by the National MS Society. Among findings from the 50 projects supported through this $10 million initiative was the possibility that the female hormone estriol may help protect against the immune attacks that underlie MS. Estriol levels rise significantly during pregnancy, when most women's MS disease activity declines. This led some to suspect that estriol may be responsible for this easing of symptoms during pregnancy.

According to Dr. Voskuhl, in using estriol they "aim to simulate some of the disease protection offered by pregnancy. We are very enthusiastic about this new agent since it has decades of known human safety experience throughout Europe and since it will be given as a pill, not a shot."

Dr. Voskuhl (University of California, Los Angeles) and others explored this lead in mice with MS-like disease, and later, with National MS Society support, Dr. Voskuhl conducted a small, early-phase trial of estriol in 12 women with MS. The results showed decreases in disease activity during estriol treatment in women with relapsing-remitting MS.

Trial Details/Eligibility

The two-year study is a double-blind, placebo-controlled trial that will take place at seven sites in the U.S. (listed below). Investigators will administer estriol in pill form to women between the ages of 18-50 who are fairly newly diagnosed with relapsing-remitting MS. The oral treatment will be given in combination with subcutaneously injected Copaxone, a standard treatment for MS, for 2 years. The team is evaluating effects of the treatment combination on relapse rates and several clinical and magnetic resonance imaging measures of disability progression.

Seven Centers Recruiting Patients

The estriol trial is taking place at seven medical centers across the U.S. Women between 18-50 who are newly diagnosed and are interested in participating in this clinical trial should contact the nearest site to discuss their eligibility:

Institution	Coordinator	Phone
University of California, Los Angeles	Mike Montag	310-825-7313
Washington University, St. Louis	Joanne Lauber, RN	314-362-3371
Univ. Med. & Dent. of New Jersey, New Brunswick	Yaritza Rosario	732-235-7099
Ohio State University, Columbus	Lisa Hafer	614-293-7877
University of Chicago	Mildred Valentine	773-702-9812
University of Utah, Salt Lake	Julia Klein	801-582-1565 x2014
Wayne State University, Detroit	Elisabetta Levcovici	313-966-5068

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