



Multiple
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Society of
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Medical Update Memo

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Small study combines Novantrone and Copaxone as potential MS treatment

SUMMARY

British researchers report results from a very small, uncontrolled study of Copaxone® (glatiramer acetate) combined with Novantrone® (mitoxantrone). The study involved 27 people with very active relapsing-remitting MS. Further research is needed to determine the safety and effectiveness of this and other such combinations.

DETAILS

Researchers report that giving Copaxone® (glatiramer acetate) after a short course of Novantrone® (mitoxantrone) appeared to be safe and effective in a very small uncontrolled study involving 27 people with very active relapsing-remitting MS. Drs. Mike Boggild, Jason Ramtahal and colleagues (The Walton Centre for Neurology and Neurosurgery, Liverpool, UK) report their results in an upcoming issue of *The Journal of Neurology*.

Novantrone is approved in Canada for treating some types of cancer and is used “off label” for MS to reduce neurologic disability and/or the frequency of clinical relapses (attacks) in worsening relapsing-remitting MS (disease characterized by clinical attacks without complete remission), secondary progressive MS (disease that has changed from relapsing-remitting to progressive at a variable rate), and progressive-relapsing MS (disease characterized by a gradual increase in disability from onset with clear, acute relapses).

The Walton Centre team administered different doses of Novantrone (given by IV infusions at different intervals) to a total of 27 people. Most received five pulses total of Novantrone -- at 20 mg monthly for three months, then at 10 mg every three months

(months 0,1,2,5, and 8). Copaxone (20 mg daily injected under the skin) was introduced between the third and fourth pulses of Novantrone.

The investigators observed a sustained reduction in the annual rate of relapses. Disability remained stable or improved in all participants for an average of 36 months from the beginning of treatment. Two relapses have occurred, both in people previously treated with Copaxone.

One person developed acute leukemia nine months after completion of Novantrone therapy. Other side effects included leucopenia (reduction of white blood cells) which improved with dose reduction of Novantrone, and menstrual disorders that improved with withdrawal of Novantrone. No cardiac problems occurred. One person stopped Copaxone therapy after 11 months because of recurrent injection site reactions.

It should be noted this is a very small study which was conducted unblinded and without a non-treated control group of participants for comparison. In addition, Novantrone is known to be associated with leukemia and congestive heart failure with fatalities particularly at higher cumulative doses. According to medical criteria, the lifetime cumulative dose is limited to 140 mg/m², which would mean about eight to 12 doses over two to three years, although major side-effects with fatalities have been seen at much lower doses. Studies are ongoing to determine therapeutic options that take advantage of the immune-suppressing benefits of Novantrone for active MS while limiting its potential risks.

Further research is needed to determine the safety and effectiveness of this and other such combinations. The investigators continue to follow this group of patients to evaluate the long-term safety of this treatment, and are initiating a larger controlled study to compare this combination against Rebif® (interferon beta-1a) in people with active relapsing-remitting MS in multiple centres in the United Kingdom.

[With information from the National MS Society (USA)]

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