



Multiple
Sclerosis
Society of
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en plaques



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Medical Update Memo

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Recruitment of participants underway for combination therapy study

SUMMARY

Investigators are seeking participants for the first large-scale clinical trial testing the combined use of interferon beta-1a (Avonex®) and glatiramer acetate (Copaxone®) to treat relapsing-remitting multiple sclerosis. Approximately 80 medical centres in North America - including three in Canada - are recruiting people who have relapsing-remitting MS for the study, called the CombiRx trial. The combination therapy will be compared to the use of either agent alone for a period of 36 months. All participants will receive at least one active medication, and there will not be a placebo-only treatment arm.

DETAILS

Investigators at three Canadian MS clinics are taking part in the first large-scale clinical trial testing the combined use of interferon beta-1a (Avonex®) and glatiramer acetate (Copaxone®) to treat relapsing-remitting multiple sclerosis. The clinics are located in Ottawa, Toronto and Calgary. (See details below for enrolment and contact information.)

This study, called the CombiRx trial, will compare the combined use of Avonex and Copaxone to the use of either agent alone for a period of 36 months. All participants will receive at least one active medication, and there will not be a placebo-only treatment arm. The study is funded by the NIH's National Institute of Neurological Disorders and Stroke (USA). Lead investigator is Fred D. Lublin, MD (Mount Sinai School of Medicine, New York, NY).

An important ancillary study to this trial will examine genetic and other biological markers at baseline and at least one additional point during the study. The hope is that these biological markers will provide a means for identifying, in the future, those people with more aggressive disease as well as those who respond or fail to respond to therapy. Such markers would have considerable value in the management of MS.

Treatment with disease-modifying agents can reduce future disease activity and improve quality of life for many individuals with relapsing forms of MS. However, researchers continue to explore whether using these agents in combination can enhance their effectiveness. A previous, smaller pilot trial of the combination therapy suggested it was safe and warranted further study.

The primary objective of the study is to determine whether this combination treatment is effective in reducing relapse rates, when compared to treatment with either drug alone. Secondary objectives are to determine the safety and tolerability of this combination.

Eligibility for participation:

People eligible for participation include men and women 18-60 years of age with relapsing-remitting MS (a course of MS in which clearly defined flare-ups are followed by complete or partial recovery periods), who have experienced at least two relapses in the previous three years and have never received either agent.

Participants will be randomly assigned to receive either 1) a combination of interferon beta-1a (30 micrograms given as a once-a-week intramuscular injection) and glatiramer acetate (20 milligrams injected subcutaneously once a day); 2) interferon beta-1a and an inactive placebo delivered subcutaneously; or 3) glatiramer acetate and a placebo delivered intramuscularly. Treatment is being administered for 36 months.

Individuals who meet the study criteria may contact the research centres directly:

MS Clinic, St. Michael's Hospital, Toronto - Chantal Bidal, Research Coordinator,
(416) 864-5176

MS Clinic, Ottawa Hospital - Dawn Carle, Research Coordinator, (613) 737-8104

MS Clinic, Foothills Hospital, Calgary - Krista Warners, Research Coordinator,
(403) 944-4244

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

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