administered for 6 months, followed by a 6-month follow-up period. The investigators were careful to administer SF-36 at baseline, 3 months, 6 months, and 12 months.

The study drug prevented the development of new lesions, as measured by magnetic resonance imaging. This effect was quite dramatic. However, the study drug did not result in any significant improvement of HRQoL, as assessed by the SF-36 form.

## d. Interferon-beta-1a – the Jongen study

In a clinical trial of 284 patients, Jongen et al. (21) treated all patients with interferon-beta-1a, known by the trade name Avonex®. Response was assessed by tests for physical outcome, that is, the Multiple Sclerosis Functional Composite (MSFC), which includes a timed 25-foot walk. Response was also assessed by an HRQoL instrument, that is, the MS54QoL questionnaire. Data from the physical tests and HRQoL tests were captured at baseline and at 3, 6, 12, 18, and 24 months.

The MSFC scores did not change significantly.

In contrast, HRQoL scores did improve. The physical score component of the HRQoL instrument improved somewhat, while the mental score component of the HRQoL instrument improved only slightly. The authors examined the subgroups of the study population, and in reviewing data from the subgroups, the authors concluded that, "after 2 years of treatment, HRQoL was increased, especially in younger patients with low disability."

## e. Glatiramer acetate – the Zwibel study

Zwibel et al. (22) conducted a clinical trial on patients with multiple sclerosis. All patients received daily injections of glatiramer acetate. The study involved 805 patients, some of whom had already been treated with interferon-beta-1b, while the rest were treatment-naive. Glatiramer acetate is a synthetic random polypeptide, containing L-alanine, L-glutamate, L-lysine, and L-tyrosine. The drug inhibits Th1-type immune response, and promotes Th2-type immune response (23,24).

This was a single arm study, that is, all patients received the study drug. Efficacy was assessed by the EDSS scale every 6 months, while safety was assessed every 3 months, for a period of up to 3.5 years.

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