Benefit of interferon beta-1a on MSFC progression in secondary progressive MS.

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Corporate Authors

IMPACT Investigators

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Abstract

BACKGROUND: Interferon beta-1a (IFNbeta-1a, Avonex) is efficacious in relapsing forms of MS. Studies of other IFNbeta preparations in secondary progressive MS (SPMS) yielded conflicting results. This study was undertaken to determine whether IFNbeta-1a slowed disease progression in SP-MS.

METHODS: A total of 436 subjects with SPMS and Expanded Disability Status Scale (EDSS) score 3.5 to 6.5 were randomized to receive IFNbeta-1a (60 micro g) or placebo by weekly intramuscular injection for 2 years. The primary outcome measure, used for the first time in a large-scale MS trial, was baseline to month 24 change in the MS Functional Composite (MSFC), comprising quantitative tests of ambulation (Timed 25-Foot Walk), arm function (Nine-Hole Peg Test [9HPT]), and cognition (Paced Auditory Serial Addition Test [PASAT]).

RESULTS: Median MSFC Z-score change was reduced 40.4% in IFNbeta-1a subjects (-0.096 vs -0.161 in placebo subjects, \( p = 0.033 \)), an effect driven mainly by the 9HPT and PASAT. There was no discernible benefit on the EDSS, which in this range principally reflects walking ability. IFNbeta-1a subjects had 33% fewer relapses \( (p = 0.008) \). There was significant benefit on eight of 11 MS Quality of Life Inventory subscales. New or enlarging T2-hyperintense brain MRI lesions and
gadolinium-enhancing lesions were reduced at months 12 and 24 (both p < 0.001). IFN beta-1a was well tolerated by the majority of subjects. Neutralizing antibodies developed in 3.3% of IFN beta-1a-treated subjects.

**CONCLUSIONS:** IFN beta-1a demonstrated benefit on MSFC progression, relapses, quality of life, and MRI activity in SPMS.