

Medical Update Memo

January 29, 2010

Sustained-release oral fampridine in multiple sclerosis: a randomised, double-blind, controlled trial.

Summary

Clinical studies suggested that fampridine (4-aminopyridine) improves motor function in people with multiple sclerosis. This phase III study assessed efficacy and safety of oral, sustained-release fampridine in people with ambulatory deficits due to multiple sclerosis. *Lancet*. 2009 Feb 28;373(9665):697-8.

Details

301 patients with any type of multiple sclerosis were enrolled in a randomised, multicentre, double-blind, controlled phase III trial and were treated for 14 weeks with either fampridine (10 mg twice daily; n=229) or placebo (n=72), using a computer-generated sequence stratified by centre. The breakdown for type of MS was:

Type of MS	Number	% of Study Population
Relapsing Remitting	47	31
Primary Progressive	21	13
Secondary Progressive	77	51
Progressive Relapsing	6	6

The primary outcome measure was defined as a consistent improvement on timed 25-foot walk. The 12-item multiple sclerosis walking scale was used to validate the clinical significance of the response criterion. Efficacy analyses were based on a modified intention-to-treat population (n=296), which included all patients with any post-treatment efficacy data.

The proportion of timed walk responders was higher in the fampridine treated group (78/224 or 35%) than in the placebo group (6/72 or 8%; $p < 0.0001$). The average change from baseline for treated responders was on 0.5 feet per second over a 25 foot timed walk. Improvement in walking speed in this group was maintained throughout the treatment period. Timed walk responders showed greater improvement in 12-item multiple sclerosis walking scale scores (-6.84, 95% CI -9.65 to -4.02) than timed walk non-responders (0.05, -1.48 to 1.57; $p = 0.0002$). Safety data were consistent with previous studies.

Of the patients in the treated group, 7% reported 1 or more serious adverse events. These included but were not limited to; urinary tract infection, severe anxiety, sepsis related to a community acquired pneumonia, and seizure.

Fampridine improved walking ability in some people with multiple sclerosis. This improvement was associated with a reduction of patients' reported ambulatory disability.

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