

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

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Abstract

BACKGROUND: 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. **METHODS:** We undertook a randomised, multicentre, double-blind, controlled phase III trial. We randomly assigned 301 patients with any type of multiple sclerosis to 14 weeks of treatment with either fampridine (10 mg twice daily; n=229) or placebo (n=72), using a computer-generated sequence stratified by centre. We used consistent improvement on timed 25-foot walk to define response, with proportion of timed walk responders in each treatment group as the primary outcome. We used the 12-item multiple sclerosis walking scale 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 study is registered with ClinicalTrials.gov, number NCT00127530. **FINDINGS:** The proportion of timed walk responders was higher in the fampridine group (78/224 or 35%) than in the placebo group (6/72 or 8%; p<0.0001). Improvement in walking speed in fampridine-treated timed walk responders, which was maintained throughout the treatment period, was 25.2% (95% CI 21.5% to 28.8%) and 4.7% (1.0% to 8.4%) in the placebo group. 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. **INTERPRETATION:** Fampridine improved walking ability in some people with multiple sclerosis. This improvement was associated with a reduction of patients' reported ambulatory disability, and is a clinically meaningful therapeutic benefit.