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RESEARCH/CLINICAL UPDATE

Keyword:	**Fampridine-SR**
Section:	TREATMENTS, INVESTIGATIONAL

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MS TRIAL ALERT:
FAMPRIDINE-SR STUDY ENROLLING PATIENTS WITH MS

Summary: Investigators at approximately 35 centers in the United States and Canada are enrolling participants in a 14-week clinical trial testing the safety and effectiveness of Fampridine-SR (an oral, sustained-release formula of 4-aminopyridine being developed by Acorda Therapeutics) compared with inactive placebo to improve walking ability in 200 people with all types of multiple sclerosis.

Rationale: Fampridine-SR blocks tiny pores, or potassium channels, on the surface of nerve fibers, and thus may improve the conduction of nerve signals in nerve fibers whose myelin coating has been damaged by MS. Dr. Andrew Goodman (University of Rochester) recently presented the results of a previous phase 3, placebo-controlled study of Fampridine-SR in 301 individuals with all types of MS. Thirty-five percent of those on active therapy experienced an average of 20% improvement in walking speed (in the timed 25-foot walk), which was maintained over the 14 weeks of therapy. Two serious adverse events that led to the discontinuation of dosing were anxiety in one participant and a seizure during a serious infection in another. The current study was designed based on these and other study results.

Eligibility and Details: People eligible for participation include individuals 18-70 years of age with any form of clinically definite MS. Participants must have adequate cognitive function to understand and sign the informed consent, and must be able to perform the required study procedures, which include tests of walking speed. Participants should be able to walk, although with some difficulty. Women who are pregnant or breastfeeding are excluded from participating.

Participants will be randomly assigned to receive either Fampridine-SR or placebo. Individuals on a disease-modifying therapy are permitted to participate if disease activity is stable, but should discuss the details of their therapy with the study coordinator. The primary outcome measure for the study is an improvement in walking ability, which will be measured using the "Timed 25-Foot Walk" test. Secondary outcomes include measurements of leg strength and muscle spasticity (stiffness and involuntary muscle spasms), and the "MS Walking Scale-12." Safety is being evaluated based on reports of side effects, measurement of vital signs, blood tests, and electrocardiograms.

Contact: Below is a list of the sites participating in the study. All sites are not yet enrolling patients. For information about study enrollment at a site near you, please call 877-617-2494, toll-free, weekdays from 10:00 a.m. to 4:00 p.m. (EST).

SITES:

United States
Neurological Associates, Fayetteville, AK
Barrow Neurology Clinic, St. Joseph's Hospital and Medical Center, Phoenix, AZ
HOPE Research Institute, Phoenix, AZ
USC, Keck School of Medicine Health Care Consultation Center, Los Angeles, CA
Alta Bates Summit Medical Center - Research and Education Institute, Berkeley, CA
UC Davis, Sacramento, CA
Yale University MS Center, New Haven, CT
Shepherd Center, Atlanta, GA
University of Chicago, Chicago, IL
Consultants in Neurology, Ltd., Northbrook, IL
Indiana University MS Center, Indianapolis, IN
Associates in Neurology, PSC, Lexington, KY
Maryland Center for MS, Baltimore, MD
Lahey Clinic, Lexington, MA
Wayne State University, Detroit, MI
The Schapiro Center for MS, Golden Valley, MN
Washington University School of Medicine, St. Louis, MO
Advanced Neurology Specialists, Great Falls, MT
Gimbel MS Center at Holy Name Hospital, Teaneck, NJ
UMDNJ, Newark, NJ
Corinne Goldsmith Dickinson Center for MS, New York, NY
SUNY Stony Brook, Stony Brook, NY
University of Rochester, Rochester, NY
Columbia University Multiple Sclerosis Clinical Care Center, New York, NY
Jacobs Neurological Institute Buffalo General Hospital, Buffalo, NY
CMC - Neuroscience & Spine Institute, Charlotte, NC

Wake Forest University, Winston-Salem, NC
Raleigh Neurology Associates, Raleigh, NC
The Center for Neurological Services, Bismarck, ND
Cleveland Clinic Foundation, Cleveland, OH
Ohio State University MS Center, Columbus, OH
Oregon Health & Science University, Portland, OR
Thomas Jefferson University Physicians, Philadelphia, PA
Fletcher Allen Health Care, Burlington, VT
Neurological Research Center, Inc., Bennington, VT
MS Center at Evergreen, Kirkland, WA
CAMC Health Education & Research Institute, Charleston, WV
Center for Neurological Disorders of Aurora, St. Luke's Medical Center, Milwaukee, WI

Canada
Foothills Medical Center, Calgary, Alberta
University of British Columbia, Vancouver Coastal Health Research Institute, Vancouver, BC
River Valley Health, Fredericton, New Brunswick
QEII Health Sciences Centre, Nova Scotia Rehabilitation Centre Site, Halifax, Nova Scotia

-- Research and Clinical Programs Department