

polio network news

Research reports

NAPPS Preliminary Data

Pyridostigmine was not found to provide significant benefits with respect to quality of life, fatigue, or isometric muscle strength compared with placebo, although a trend was noted towards increased strength in very weak muscles.

NAPPS?

The North American Post-Poliomyelitis Pyridostigmine Study (NAPPS) received support from ICN Pharmaceuticals, the company that markets and distributes pyridostigmine as Mestinon. Currently approved for the treatment of myasthenia gravis, Mestinon is an oral anticholinesterase agent which improves the transmission of impulses across the neuromuscular junction, the interface of nerve and muscle cells.

NAPPS was initiated by participating investigators in five medical centers in the United States and Canada: Neil R. Cashman, MD and Daria A. Trojan, MD, Montreal Neurological Institute and Hospital, Montreal, Quebec, Canada; Burk Jubelt, MD, SUNY Health Science Center, Syracuse, New York; James Agre, MD, PhD, University of Wisconsin at Madison; Theodore L. Munsat, MD and Dave Hollander, MD, New England Medical Center, Boston, Massachusetts; and Robert Miller, MD, California Pacific Medical Center, San Francisco.

Conducted during 1996-97, NAPPS was a double-blind,

randomized, placebo-controlled trial that followed 126 patients given either 60 mg of pyridostigmine three times daily or placebo for six months; 64 received pyridostigmine and 62 received placebo. All participants completed the study.

RESULTS

During the six-month course of the study, 70 percent of patients on pyridostigmine and 73 percent of patients on placebo had at least eighty percent compliance with the medication. The study medication was well tolerated: four severe adverse events were observed during the trial, three of which occurred in pyridostigmine-treated patients. Some relative contraindications to pyridostigmine include certain cardiac arrhythmias, increased bronchial secretions and reactivity, and some urological disorders.

The study did not show a difference between pyridostigmine and placebo patients in terms of their health-related quality of life, fatigue, (as measured by two fatigue scales), and most measures of isometric muscle strength.

Health-related quality of life was assessed with the short form health survey — 36 (SF-36). Fatigue was measured with two subjective fatigue scales: the fatigue severity scale and the Hare fatigue symptom scale. Muscle strength was measured as isometric strength in twelve muscle groups in each patient by a modified Tufts quantitative neuromuscular exam.

Dr. Trojan, who presented at the annual meeting of the American Academy of Physical Medicine and Rehabilitation (AAPM&R) in Atlanta in November, noted that there was a nonsignificant increase in strength in very weak muscles (1% to 25% of predicted normal strength) in pyridostigmine-treated patients at six months of treatment.

Dr. Trojan also commented that the results were unexpected and did not reflect the investigators' clinical impression that there appeared to be a clear benefit in some patients.

Another purpose of the study was to assess the effect of Mestinon on IGF-1 (insulin-like growth factor-1) which is believed to support the sprouting of motor neurons. IGF-1 is known to decrease with age and may be a contributing factor to the onset of post-polio syndrome.

IGF-1 serum analyses have not yet been completed. Data analysis for the trial is still ongoing. The open trial phase of the study is still in progress. Therefore, this is not "the last word" on the study. We expect the NAPPS trial to be submitted for publication in the next few months.

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ICN Pharmaceuticals has no plans to fund further research into the use of Mestinon for post-polio fatigue. During these few years of affiliation, considerable literature aimed at educating health professionals has been created under the auspices of the Post-Polio Task Force, supported by an unrestricted educational grant from ICN Pharmaceuticals (See *Polio Network News*, Vol. 13, No. 3).

Information from the Post-Polio Task Force is available at www.post-polio.org. ■

international polio network

Polio Network News (ISSN 1066-5331)
Winter 1998 ■ Vol. 14, No. 1

Polio Network News is an international newsletter for polio survivors, health professionals, and resource centers to exchange information, encourage research, and promote networking among the post-polio community.

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COORDINATED AND PUBLISHED BY:
Gazette International Networking
Institute (GINI)

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Special thanks to:

Ellen Fay Peak, volunteer editor;
Lauro S. Halstead, MD; Daria Trojan, MD;
and Marianne Weiss, MS, PT

Annual subscription:

USA: \$20 ■ Canada, Mexico, and
Overseas surface: \$25 (US dollars only)
Overseas air: \$30 (US dollars only)

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Research reports

Static Magnet Fields: Their Effect in the Control of Pain in Disabled Patients

The following is a summary of a poster presentation at the November 1997 meeting of the American Academy of Physical Medicine & Rehabilitation by Carlos Vallbona, MD (Baylor College of Medicine/Veterans Affairs Medical Center, Houston, Texas); Carlton F. Hazlewood, PhD; Gabor Jurida, MD.

Acute and chronic pain due to myofasciitis or degenerative joint disease may interfere with the rehabilitation of patients with disabilities. Analgesics and physical therapy are useful in pain management, but not always successful. We demonstrated the effectiveness of magnetic fields in a double-blind randomized clinical trial involving 50 patients with post-polio syndrome who reported muscular or arthritic-type of pain. The placement of a magnet that delivered a static field of 300 to 500 Gauss over a clearly identified trigger point relieved the pain rapidly and the effect lasted for some time after removal of the device. We have used similar magnets in other disabilities with good results. There is abundant literature on the biologic effects of magnetic fields, but the exact mechanisms of pain relief have not been elucidated. There may be a direct effect on pain receptors and/or an indirect change in perception due to the release of enkephalins in the reticular system. Specific issues that must be explored are: (1) dose response; (2) duration of effect; (3) synchronous response to magnets placed

on several areas; (4) differences of effect of various sizes and shapes of the magnetized device; and (5) cost effectiveness of pain management with magnetic fields.

Vallbona and colleagues' study of magnetic therapy in post-polio was also recently published.

Vallbona, C., Hazlewood, C., Jurida, G. (1997). Response of pain to static magnetic fields in post-polio patients: a double-blind pilot study. *Archives of Physical Medicine & Rehabilitation*, 78, 1200-1203.

Carlos Vallbona, MD, professor of family and community medicine and physical medicine and rehabilitation at Baylor and director of the Post-Polio Clinic at The Institute for Rehabilitation and Research (TIRR), and colleagues evaluated magnet therapy in adults diagnosed with post-polio syndrome who were experiencing arthritic pain in the joints or had identifiable points of pain in their muscles.

Thirty-nine women and eleven men participated in the study. Most were in their 50s and had developed post-polio syndrome during their 40s.

All patients were asked to press on the "trigger point" where they felt the severest pain and rank that pain on a scale of one to 10, with 10 being the worst. The patients were then randomly given an active or inactive magnet to strap against their trigger point for 45 minutes. After the magnets were removed, patients rated the intensity of their pain again.