ALS clinical trial follows promising animal study

Patients with amyotrophic lateral sclerosis (ALS), or Lou Gehrig’s disease, will be recruited starting in late March for a VA-funded nationwide study testing the safety of sodium phenylbutyrate as a life-extending treatment. The drug, which has been used for years as a cancer therapy, significantly extended the lives of ALS mice in a study published this month in the Journal of Neurochemistry.

ALS involves the destruction of cells in the brain and spinal cord that control muscle movement, resulting in gradual muscle wasting and loss of movement. Only 20 percent of ALS patients live longer than five years after onset. The disease usually strikes people between ages 40 and 70. There is no cure, but several potential new treatments are being investigated, including sodium phenylbutyrate, which is thought to work by correcting the “death messages” transmitted to the neurons affected in ALS.

“We do not have a cure, but we do have a therapy that we hope will slow the disease,” said Robert J. Ferrante, PhD, MSc, a neurology researcher at the Edith Nourse Rogers Memorial Veterans Hospital in Bedford, Mass. Ferrante and two colleagues—Dr. Merit Cudkowicz of VA and Massachusetts General Hospital (MGH), and Dr. Robert Brown Jr. of MGH and Harvard Medical School—conducted the animal study and are coordinating the new clinical trial, to take place at six VA sites and two non-VA sites nationwide. The effort is part of a

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VA funds new high-tech rehabilitation center

A group of investigators at the Cleveland VA Medical Center will receive $850,000 per year over five years from VA to create a new rehabilitation center of excellence that will merge state-of-the-art technologies to help veterans with spinal cord injury, limb loss and other serious disabilities. The center will build on research at the existing Cleveland Functional Electrical Stimulation (FES) Center, established by VA in 1991.

According to Ronald Triolo, PhD, executive director of the new Advanced Platform Technology Center, the initiative will bridge the gap between technologies being

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Vietnam veteran provides patient perspective at HSR&D national meeting

“At the VA I see the end result of the scientific studies you perform, ultimately advancing the collective knowledge of how to care for people with chronic illnesses. I see advances in patient care through better treatment plans and medications.”

These were the words of Ken Dexter, who served as a gunner and crew chief aboard a Cobra attack helicopter in Vietnam and who today receives medical care at the Michael E. DeBakey VA Medical Center in Houston. A guest speaker at the recent Health Services Research and Development national meeting, Dexter talked candidly about his experiences with VA’s health system and with medical care in general, providing a patient’s perspective on the meeting’s theme: improving chronic care.

While Dexter offered several ideas to improve VA care—such as giving patients easier access to hospital administrators, and encouraging physicians to be more proactive in informing patients about new treatments—his talk largely focused on how VA researchers and clinicians have enhanced his quality of life.

“I am sure you rarely get any sort of firsthand acknowledgment that your efforts have helped anyone,” said Dexter. “Please accept my sincerest thank-you for everything you have done, are doing, and will be doing in the future. Know that your energies and efforts have helped at least one life—mine. Every visit to the VA Medical Center in Houston reaffirms my faith that you have not given up on patients living with chronic illness. You are making a

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difference in our quality of life.”

The meeting, held Feb. 16 – 18 in Baltimore, drew some 500 researchers, clinicians and policymakers. Mark Kunik, MD, MPH, associate director of the Houston-based Center for Quality of Care and Utilization Studies, which hosted the meeting, cited the importance of improving chronic care in light of the aging veteran population. He noted that between 1992 and 2000, the youngest cohort of VA patients shrunk by 10 percent, while the oldest cohort grew by more than 10 percent.

Stephan Fihn, MD, MPH, acting chief research and development officer, spoke about recent significant contributions made by HSR&D investigators, such as establishing the cost-effectiveness of routine HIV screening; increasing access to specialty care in nursing homes; and assessing a VA bar-code medication system that reduces medication errors. Fihn also outlined upcoming priority areas for funding, such as improving the continuum of care for new veterans and active-duty personnel seeking VA care, and improving care for women veterans and those who need long-term care.

Jonathan Perlin, MD, PhD, MSHA, VA’s acting under secretary for health, addressed participants via video and presented the 2005 Under Secretary’s Award for Outstanding Achievement in Health Services Research to Rodney Hayward, MD, director of HSR&D’s Center for Practice Management and Outcomes Research in Ann Arbor. Hayward was cited for his innovative leadership in improving health care for veterans, especially those with diabetes. Hayward is also noted for his work in developing more reliable approaches to tracking medical errors.

Edward Wagner, MD, MPH, director of the MacColl Institute for Healthcare Innovation in Seattle, delivered a keynote talk on dealing with chronic illness in primary care. He emphasized collaboration across the health care continuum—including primary care doctors, specialists and community resources—to better serve patients.

More information about the meeting, including abstracts, is available on the HSR&D website at www.hsrd.research.va.gov/about/national_meeting.

Center (cont. from pg. 1)

developed for general use and the specific needs of disabled veterans.

“The work of the APT Center will be to apply the creativity and advancements we see every day in consumer product technology to the needs of our veterans,” he said.

Early priorities of the center will include sensory and implanted control of prosthetic limbs; sensors for monitoring various biological functions; and accelerated wound healing. The researchers expect to incorporate novel biocompatible materials, innovative microelectromechanical devices, and nanotechnology.

For more information on existing work at the Cleveland FES Center visit http://fescenter.case.edu.

ALS (cont. from pg. 1)

“bench to bedside” translational program focused on motor-neuron disease that Ferrante and colleagues have built over the past 15 years.

The only approved drug for ALS is riluzole, which Ferrante said offers only “marginal benefit.” He said support for the sodium phenylbutyrate trial reflects the increasing willingness of VA and other funding agencies to invest in translational research aimed at fast-tracking potentially valuable new treatments.

“There has been a great deal of energy, both in NIH and VA, to ensure that these therapies move forward,” said Ferrante. “A lot of credit goes to [VA] Central Office—they really want to bring some of these therapeutic regimens to patients.”

The VA sites that will host the ALS trial are Bedford, Houston, Lexington, KY; Syracuse, Durham and Iowa City. The non-VA sites are MGH and Johns Hopkins University in Baltimore. For more information call (781) 687-2884.

Director of operations named for ORD

William J. (John) Slauson was named director of operations for the Office of Research and Development (ORD). Slauson, who retired as a Lt. Colonel in the U.S. Air Force, previously worked as a chief administrative officer at both the National Eye Institute and the National Institute of Neurological Disorders and Stroke. He holds a master’s in health services administration from The George Washington University, as well as a bachelor’s in human resources administration, and is board-certified by the American College of Healthcare Executives.
Middle-aged and older people with schizophrenia showed social and cognitive improvements after six months of specialized psychotherapy, reported VA researchers and colleagues in the March issue of the American Journal of Psychiatry. The study was one of the first in the United States to test psychotherapy for schizophrenia. It was also among the first trials of a therapeutic intervention designed especially for older patients with the disease.

“Despite being ill for decades, these patients were able to learn the new skills taught in our therapy model, and began to think about their unusual beliefs about the world in more realistic ways,” said senior author Dilip V. Jeste, MD, a psychiatrist at the VA San Diego Health Care System and the University of California, San Diego.

The researchers used a combination of cognitive behavioral therapy (CBT) and social skills training (SST). CBT teaches patients to identify and challenge their erroneous and problematic thoughts and beliefs. SST builds skills in hygiene, stress management, conversation and other areas. The researchers customized the combination therapy to address issues common among aging patients, such as memory loss, disability, and low confidence in their ability to learn new skills.

The study included 76 patients, ages 42 to 74, half of whom received the special psychotherapy. All remained on their antipsychotic medications. These drugs usually help psychiatric symptoms but do not adequately improve social functioning.

After six months, those receiving the psychotherapy were more likely to engage in social activities. The researchers say these improvements may have come about because the CBT helped them reverse negative thoughts such as “I’ll be harmed if I go out,” or “It won’t be fun,” or “I won’t be able to do it.”

The therapy patients also demonstrated better coping skills and more rational thinking, compared to the group receiving only medication.

Psychotherapy is recommended in clinical guidelines for schizophrenia as an adjunct to drugs, based largely on the results of British studies. But the treatment is often not given, partly due to the perception among healthcare providers that it increases costs without substantial benefits. “Most patients do not receive this recommended intervention, and older patients are even less likely than younger patients to receive it,” said Jeste.

The researcher points out, however, that psychotherapy for schizophrenia may pay for itself in the long run because recipients may tend to spend less time in the hospital and more time at work and social activities. He noted that VA recently allocated funding for enhanced delivery of CBT and other psychosocial interventions for veterans with schizophrenia.

Jeste’s study collaborators, all with VA and UCSD, were lead author Eric Granholm, PhD; John R. McQuaid, PhD; Fauzia Simjee McClure, PhD; Lisa A. Auslander, PhD; Dimitri Perivoliotis, MS; Paola Pedrelli, MA; and Thomas Patterson, PhD.

The study was funded by VA and the National Alliance for Research on Schizophrenia and Depression.

VA investigator receives $14-million NIH grant to expand training

Molly Carnes, MD, MS, director of the Women’s Health Program at the Madison, Wis., VA Medical Center, has received a $14-million grant from the National Institutes of Health to expand her work in training clinical researchers. Carnes, who also directs the University of Wisconsin Center for Women’s Health Research, will aim to develop multidisciplinary teams of investigators to tackle the nation’s clinical-research agenda, as outlined in NIH’s Roadmap initiative.

The five-year grant, titled “Training and Education to Advance Multidisciplinary Clinical Research,” is one of seven Roadmap training grants issued recently by NIH. The awards are the largest training grants ever given by the agency. Carnes’ program will build on existing training efforts at her site, such as the Clinical Investigator Preparatory Program and the Women’s Health and Aging Training Program. The new grant will focus on 10 areas of medicine: aging and geriatrics; asthma; cancer; cardiovascular diseases; child and adolescent health; epilepsy; healthcare environment, technology and communication; nutrition and obesity; tobacco and alcohol intervention; and women’s health and underserved populations. The initiative will involve some 72 VA and University of Washington faculty as primary mentors and 100 more as secondary mentors.

To learn more about Carnes’ work visit www.womenshealth.wisc.edu.
Research Currents to reflect feedback from recent email and Web survey

This newsletter conducted an informal Web-based survey recently to gauge satisfaction with the publication in the VA research community. Emails with a link to the survey were sent to some 3,800 investigators and research administrators. Nearly 460 of them responded, for a response rate of 12 percent.

The responses were largely positive. For example, in Likert-scale questions asking respondents to rate the newsletter for “interest,” “usefulness of information,” “style or quality of writing,” “layout,” and “ease of reading,” the highest-scoring answer for each was 4 on a scale of 1 to 5, with 5 being the best. Three open-ended questions generated an interesting array of comments, most of them positive and many containing useful criticism or suggestions.

One goal of the survey was to determine whether to continue both print and electronic versions of the publication. Asked to choose between the two options, most respondents said they preferred electronic, but a considerable number expressed a preference for the hard copy (59 vs. 36 percent). Current plans are to continue both versions.

Based on suggestions or concerns raised by significant numbers of respondents, we plan to integrate the following changes in future issues:

- Include more articles on funding (trends, opportunities, etc.);
- Emphasize content that is relevant to wide cross-section of researchers—for example, budget, policies, regulations;
- Provide more coverage of findings in basic and behavioral science;
- Focus more on translation of findings into patient care;
- Provide more Web links—for example, to researchers’ sites;
- Run the “Recent Publications” section (included in most issues) in slightly smaller type, to include a wide variety of publications in less space;
- Highlight work at smaller facilities more frequently;
- And, in the email that is sent with the link to the PDF of the newsletter, provide bullet points previewing contents.

Further feedback is welcome and can be sent to R&D Communications at researchinfo@vard.org.

Research methodology workshops slated for June

Online registration is now underway for the Seattle Epidemiologic Research and Information (ERIC) Seventh Annual Epidemiology, Biostatistics and Clinical Research Methods Summer Session, taking place June 20–24, 2005, on the University of Washington campus. New classes this summer include Health Economics, taught by VA Health Economics Resource Center (HERC) members Mark W. Smith, PhD, and Todd H. Wagner, PhD; and Psychiatric Epidemiology, taught by John Breitner, MD, PhD, director of the Seattle VA’s Geriatric Research, Education and Clinical Center, and Jack Goldberg, PhD, lead epidemiologist for the Vietnam Era Twin Registry. For more information visit www.eric.seattle.med.va.gov.