Research

Did You Know

CSL Behring UK Ltd. has launched the Hizentra Dosing Calculator App. Designed for use on iPhone and Android handsets, the app assists healthcare professionals with dosage calculation when administering Hizentra (human normal immunoglobulin, SCIG). It will calculate the correct volume of Hizentra to be infused based upon entry of only two key pieces of information: a patient's weight and the weekly dosage required.

According to Eddie Owens, general manager, CSL Behring UK Ltd., “We see that healthcare professionals are clearly using mobile technology to access health information, and for us to engage with this growing target audience, we need to be present in this medium. The new Hizentra Dosing Calculator App aims to meet the demand that healthcare professionals have to access sound medical data from anywhere and at anytime.”

The app can be downloaded and installed for free directly from the phone, by going online to the iTunes store at http://itunes.apple.com/gb/app/hizentra-dosing-calculator/id483147404, or by visiting Google Play at https://play.google.com/store/apps/details?id=com.nitrogen.hizentra_dose#?t=W251bGw&hl=en&gl=US.

Technology

CSL Launches Hizentra Dosing Calculator App

New study results suggest that treatment with Privigen [immune globulin intravenous (Human), 10% Liquid], an intravenous immunoglobulin (IVIG), may lead to improvement in function in patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

The Privigen Impact on Mobility and Autonomy (PRIMA) trial at the Peripheral Nerve Society Inflammatory Neuropathy Consortium Meeting in Rotterdam, Netherlands, a prospective, multicenter, open-label, single-arm study, investigated the efficacy and safety of Privigen in previously IVIG-treated and untreated patients with CIDP. The study achieved its primary efficacy endpoint, which was the percentage of patients responding — as measured by the Inflammatory Neuropathy Cause and Treatment (INCAT) scale — at study completion compared to baseline. The overall response rate was 60.7 percent. The 25-week treatment period permitted the observation that a response to IVIG can occur late (e.g., after more than six weeks of therapy).

The INCAT scale is used to measure a patient’s ability to perform tasks (i.e., walking, motor hand tasks, etc.). On this scale, patient scores rise with increasing weakness and disability, whereas improvement in basic motor functions is indicated by a reduction in the score. Results from this study showed that the mean overall INCAT score significantly improved from 3.7 at baseline to 2.3 at completion of treatment. Half of the responders achieved the clinically meaningful threshold by week four. This finding may encourage some treating physicians to continue IVIG therapy longer in their CIDP patients before assessing whether or not the therapy is working.

“CIDP is a rare, progressive disease that may cause permanent nerve damage, and studies show that current treatment options may not work for all patients,” said Jean-Marc Leger, MD, Hospital de la Salpetriere.

“Finding new treatment options to slow the advancement of the disease is extremely important. The results from this study are promising as they suggest that Privigen may help decrease weakness and loss of motor function in people with CIDP.”

Research

Privigen May Improve Function in CIDP Patients

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Octapharma USA has started an initiative to make Octagam (immune globulin intravenous [human] 5%), a therapy for primary immune deficiency, widely available to covered entities in the 340B Drug Pricing Program, which is managed by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA). The 340B Drug Pricing Program is available to certain hospitals, clinics and outpatient treatment facilities that qualify as “covered entities” under Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. More than 17,000 covered entity sites participate in the 340B Program, including six categories of hospitals that are generally considered safety net providers, and 11 categories of non-hospital covered entities, such as federally qualified health centers and specialized clinics and treatment centers.

“Octapharma is committed to providing therapies to treat life-threatening conditions to all patients, including those who are treated in facilities that have historically faced challenges accessing IGIV,” said Octapharma USA President Flemming Nielsen. “We are pleased that the supply of Octagam 5% is now sufficient to adequately serve 340B covered entities that have in recent years experienced difficulties in accessing specialty drugs such as IGIV at 340B discount prices. Octapharma is committed to serving patient needs, regardless of where they receive treatment, and ensuring a steady supply of Octagam 5% to all our hospital customers.”

Octapharma USA intends to use FFF Enterprises of Temecula, Calif., and ASD Healthcare of Frisco, Texas, as the contact point for distribution. More distributors will be added later in the year. Octapharma USA, a subsidiary of Octapharma AG, one of the world’s largest human protein product manufacturers, has been marketing octagam 5% since 2004.

Immunoglobulin Nursing Society Holds First National Conference

The Immunoglobulin Nursing Society (IgNS) held its first national conference in Orlando, Fla., August 3 through 5. The conference is a new educational initiative to develop and sustain the advancement of knowledge, education and practice of nursing in the field of immunoglobulin therapy. It featured in-depth educational sessions, hands-on practical workshops, industry-sponsored symposia and an exhibit hall featuring the top IG-related companies in the country.

Educational sessions included the latest developments in the field of IG therapy, including clinical indications, administration and adverse event prevention and management, updates on the IG clinical trial landscape and the role of nurse study coordinators, as well as an update on issues with IG reimbursement and patient advocacy. Several smaller group practical workshops were taught by leading IG nurse experts focusing on best practices in intravenous IG (IVIG) and subcutaneous IG (SCIG) administration.

“The IgNS National Conference represents a major shift in the current education and training of IG nurses who treat patients with chronic and life-threatening disorders,” said Jane Kirmse, RN, MSN, ARPN-BC, president of IgNS. “The National Conference will provide nurses with an exceptional educational program to expand their knowledge, advance their skills and experience professional growth.”
Research
Slow Release of IG May Delay Alzheimer’s Disease

Recent studies conducted by Dr. Giulio Maria Pasinetti, Saunders Family chair and professor in neurology and psychiatry at Mount Sinai School of Medicine in New York, suggests that the divergent outcomes in Alzheimer’s disease clinical studies of intravenous immune globulin (IVIG) may be due to differences in temporal administration and administered dosages. Dr. Pasinetti and his team of investigators recently found that prolonged administration of human immunoglobulin in models of Alzheimer’s disease, using a dose of immunoglobulin approximately five- to 20-fold less than equivalent doses used in Alzheimer’s disease patients, is effective at attenuating Alzheimer’s disease-type cognitive dysfunction while promoting synaptic plasticity. “This experimental observation provides a rational basis for rectifying the inconsistency of study outcomes in Alzheimer’s disease clinical trials with IVIG,” said Dr. Pasinetti. “We now have the much-needed information supporting the potential application of slow release of immunoglobulins delivered subcutaneously to delay the onset of Alzheimer’s disease, even at pre-symptomatic stages of the disease.”

Dr. Pasinetti hypothesizes that the slow release of immunoglobulins into the circulation and eventually into the brain for a protracted period of time may delay Alzheimer’s disease dementia onset and eventually its progression through epigenetic changes in the downstream gene expression of C5a-mediated pCREB-C/EBP signaling components associated with modulation of synaptic plasticity and eventually learning and memory functions.

Research
BRI and Novo Nordisk Collaborate on Autoimmune Disease Research

Novo Nordisk and Benaroya Research Institute at Virginia Mason (BRI), Seattle, Wash., have entered into a three-year collaborative agreement to potentially speed up translational research of the diagnosis and treatment of rheumatoid arthritis, inflammatory bowel disease and lupus. The agreement establishes how Novo Nordisk and BRI research scientists and clinicians will collaboratively develop studies to better understand changes in the immune systems of patients living with these autoimmune diseases. The intent is to develop better therapies and improve how these treatments are used.

“Translational research” describes a research approach that seeks to move discoveries made in laboratory, clinical or population studies more quickly into clinical care. In this specific agreement, BRI scientists and Novo Nordisk researchers at the company’s Seattle research center will work together to study samples and data registered in BRI’s biobank of patients with these diseases, as well as people with no history of autoimmune disorders. The personal information of these patients will not be disclosed.

“Improving patient care through innovation is at the heart of our company culture, and this agreement represents one way that we can work together with the larger health care research community to achieve this objective,” said Per Falk, senior vice president, Biopharmaceuticals Research Unit, Novo Nordisk. “We’re pleased to be working closely with the Seattle scientific community, which is sharing its best and brightest with us in an effort to bring new medicines for patients.”

In the United States alone, as many as 1.5 million people suffer from rheumatoid arthritis or inflammatory bowel disease, and more than half a million people suffer from lupus.

People and Places
Coronado Biosciences Inc., a biopharmaceutical company focused on the development of novel immunotherapy agents for the treatment of autoimmune diseases and cancer, has appointed Karin Hehenberger, MD, PhD, formerly senior vice president of scientific affairs, to executive vice president and chief medical officer.
A recent study conducted by Grifols suggests that the plasmapheresis process may reduce levels of low-density lipoprotein (LDL), or “bad” cholesterol, as well as total cholesterol in individuals who have high baseline levels. The study also suggests that plasmapheresis could increase levels of high-density lipoprotein (HDL) or “good” cholesterol, among individuals with low baseline levels. Plasmapheresis is a technique used to separate plasma from the remaining blood components, which are then immediately injected back into the donor at the time of the donation. Plasma obtained during plasmapheresis is used to produce lifesaving medicines for patients who have rare, genetic and life-threatening diseases.

The multicenter longitudinal study was conducted in nine plasma donor centers in the U.S., with blood analyses performed prior to plasmapheresis to measure initial levels of total cholesterol, HDL and LDL. Plasma was collected from first-time donors or from donors who had not donated plasma for at least six months. The researchers estimated from the study results that plasmapheresis could reduce the levels of LDL by more than 30 mg/dl among individuals with high levels (greater than 160 mg/dl) or higher than desirable levels (greater than 130 mg/dl) when plasmapheresis procedures are performed two to four days apart. This effect was more significant in women, in whom cholesterol could be reduced by up to 35 mg/dl. A similar reduction pattern is estimated to occur in individuals with high total cholesterol levels (greater than 240 mg/dl) or higher than desirable levels (greater than 200 mg/dl), with the reductions in these cases potentially reaching 45 mg/dl and 32 mg/dl, respectively.

However, the cholesterol-lowering effects of plasmapheresis appeared to last only as long as the procedure continued at regular intervals, with cholesterol levels gradually returning to baseline following long periods without plasmapheresis. The same pattern of reductions was seen, although to a lesser degree, when subsequent plasmapheresis procedures were performed more than 10 days apart. Among individuals with normal baseline cholesterol levels, the study results suggested that plasmapheresis would not cause significant changes.

Grifols has launched a new study into methods of treatment for Alzheimer’s disease. Known as the AMBAR (Alzheimer management by amyloid removal) study, it will investigate combined treatment using albumin plasmapheresis and intravenous immunoglobulin (IVIG) at different doses. The researchers will attempt to find synergies between the two treatments in order to reduce the frequency and volume of plasmapheresis, ultimately making the treatment experience more pleasant for patients and easier for medical professionals to administer.

AMBAR is expected to last two years and will be directed by Dr. Merce Boada, clinical head of the neurology service at the Vall d’Hebron Hospital in Barcelona. According to Dr. Boada, the study “opens up new prospects and hopes in dealing with an illness where success involves maintaining the quality of life of these patients.”
A recent study conducted at the University of Alabama at Birmingham shows that the shingles vaccine appears to be safe and effective for those suffering from autoimmune diseases. In the study, data were collected on more than 460,000 Medicare patients who had one of several rheumatic or immune-mediated diseases. Of those, more than 18,600 patients with rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis (an inflammation of the spine) or inflammatory bowel disease received the shingles vaccine. In the 42 days following vaccination, there were no cases of shingles, including among the more than 600 who were taking so-called anti-tumor necrosis factor biologics to treat their other conditions. And, there was only one case of shingles seen among all the patients during that time. More than 42 days after being vaccinated, 138 patients did develop shingles, which is in the range of the effectiveness of the vaccine. After two years of follow-up, the investigators concluded that the vaccine reduces the risk of shingles in these patients. That conclusion also was based on accounting for the type of immune disease, treatment and the use of arthritis drugs and steroids.

Because the shingles vaccine is a live vaccine, the U.S. Food and Drug Administration and other organizations say the vaccine should not be used in patients taking immunosuppressive drugs including all biologic agents and some nonbiologics because these patients may develop shingles from the vaccine virus strain. “A live attenuated vaccine reduces [shingles] risk by 70 percent and 51 percent among immunocompetent individuals 50 to 59 years and 60 years and older in two randomized, blinded trials, respectively,” the researchers wrote. And, “the risk of [shingles] is elevated by 1.5 to two times in patients with rheumatic and immune-mediated diseases such as rheumatoid arthritis and Crohn’s disease. This increase has been attributed to both the underlying disease process and treatments for these conditions.”

According to Dr. Bruce Hirsch, an attending physician in infectious diseases at North Shore University Hospital in Manhasset, N.Y., who was not involved in the study, “The findings are reassuring for a very specific group of patients.” However, the study does not address the vaccine in patients who have weakened immune systems related to other causes, Hirsch said. And, he cautions that the vaccine does have some risks and there is no long-term data on its effectiveness in these patients. “I don’t consider this study to be completely definitive,” Hirsch said. “The book isn’t closed, but I am cautiously optimistic. The vaccine seems to be safe and these kinds of patients are able to handle the vaccine and get a benefit from it.”

The study was published on July 4 in the *Journal of the American Medical Association*.