Medtronic News

First European Patients Enrolled in Largest Ever Randomised Controlled Trial of ITB Therapy(R) in Post-Stroke Patients With Severe Spasticity

TOLOCHENAZ, Switzerland, March 23, 2010 /PRNewswire via COMTEX/ -- Spasticity Affects a Significant Number of Post-Stroke Patients, [1],[2],[3] and Many are not Adequately Treated by Standard Therapy [4]

Medtronic, Inc. (NYSE: MDT) today announced the enrollment of the first European patients in the largest randomized controlled trial to date to investigate the benefits of ITB Therapy(R) (Intrathecal Baclofen) in post-stroke patients affected by spasticity. The announcement comes as the World Congress for Neurorehabilitation is taking place in Vienna, Austria.

The SISTERS study (Spasticity In STrokE Randomised Study) is expected to provide high-quality evidence on the efficacy of ITB Therapy, enabling healthcare professionals to make treatment decisions for post-stroke patients with severe spasticity who do not respond sufficiently to oral medication and physical therapy.

Stroke is a major cause of disability, with 15 million new cases each year worldwide,[5] and over one million people suffering a stroke in Western Europe every year.[6] Of these patients, up to 65 percent will suffer from spasticity as a result,[3] and for many of them, oral medication and/or physical therapy combined are not enough to manage spasticity.4 Post-stroke spasticity patients have reduced function and lower quality of life than patients without the disability.[7,8]

ITB Therapy is an approved treatment for patients with severe generalized spasticity associated with multiple sclerosis, cerebral palsy, spinal cord injury, brain injury, and stroke who do not respond to oral medication. ITB Therapy treats severe non-focal spasticity through a programmable pump, which is placed under the skin of the abdomen and connected to a catheter.

Once in place, the pump and catheter deliver anti-spastic medication directly to the site of action in the cerebrospinal fluid surrounding the spinal cord, where it may be is most effective.[9] Due to its direct administration into the spine, ITB Therapy requires a lower dosage of medication compared to oral treatments, while producing a similar reduction in spasticity with fewer possible side effects than what is often seen with higher doses of oral baclofen.[9]

"ITB Therapy has the potential to restore quality of life in patients whose lives have been completely disrupted by a stroke and the impairing and debilitating symptoms of spasticity," commented Professor Leopold Saltuari (LKH Hochzirl, Austria), global lead investigator of the SISTERS study. "With this study we are aiming to demonstrate that there is a way to manage spasticity for many of them."

The SISTERS study is an international trial, conducted in 20 sites in Europe and the US, including European centres in Austria, Belgium, Germany, Italy, the Netherlands, Spain, and the United Kingdom. The primary endpoint is the reduction of spasticity after six months of treatment with ITB Therapy and physical therapy compared to patients treated with one or more oral medications and physical therapy. Assessments include a 10-meter timed walking test, other functionality and independence tests, goal attainment scale, pain measurement, treatment satisfaction, quality of life, and safety aspects (adverse events).

In several clinical trials to date, ITB Therapy has been shown to provide a positive impact on the lives of post-stroke patients by reducing spasticity and increasing quality of life .[8,10] In other trials, 89 percent of patients with severe spasticity have seen a reduction spasticity-related pain.[11] In multiple sclerosis and spinal injury, patients experienced a 92 percent decrease in their spasticity symptoms following ITB Therapy.[12]

ITB Therapy has also been shown to improve mobility, daily functioning and quality of life, to ease patients' pain and decrease dependency on nursing care.[10,13] ITB Therapy has been shown to minimize the economic burden of spasticity, [13] by

helping physicians and caregivers improve function and comfort in patients. [11]

Some patients may experience ITB therapy drug side effects which are usually temporary and manageable by adjusting the dose. The most common side effects include loose muscles, drowsiness, nausea/vomiting, headache and dizziness. Close attention to physician's instructions is required since abrupt cessation of intrathecal baclofen can result in high fever, altered mental status, returned spasticity, and muscle rigidity, and in rare cases has been fatal. The implanted infusion system may result in complications such as infection (including meningitis), overdose or underdose resulting from programming errors or system component failures and cerebral spinal fluid leakage resulting in a spinal headache.

To date, ITB Therapy has been widely used to treat spasticity which could not be sufficiently controlled with oral medications in over 15,000 patients in Western Europe, including people with cerebral palsy and multiple sclerosis.[14]

For important safety information, please go to http://www.medtronic.eu/your-health/stroke/safety-information/index.htm.

In the US, prescribing information is available at http://professional.medtronic.com/interventions/intrathecal-baclofen-therapy/ indications-safety-and-warnings/index.htm.

(Due to the length of these URLs, it may be necessary to copy and paste this hyperlink into your Internet browser's URL address field. Remove the space if one exists.)

About Medtronic

Medtronic, Inc. (http://www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

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