Study Finds Nutraceutical No Better Than Placebo in TBI Patients

Although approved for use for treating traumatic brain injury (TBI) in nearly 60 countries, use of citicoline in a randomized trial that included more than 1,200 participants with TBI did not result in improvement in functional and cognitive status, according to a study in the Journal of the American Medical Association.

Citicoline, an endogenous (produced within the body) compound, offers potential neuroprotective properties as well as neurorepair post injury. Citicoline is widely available in the United States as a nutraceutical (product that reportedly provides health and medical benefits) and is used by patients with a range of neurological disorders, yet it has not been evaluated in a large randomized clinical trial for TBI.

The reported study evaluated the efficacy of citicoline for improving cognitive and functional status among patients with TBI. The Citicoline Brain Injury Treatment Trial (COBRIT), a Phase III randomized clinical trial, was conducted between July 2007 and February 2011. The study, which included 1,213 patients at 8 U.S. level 1 trauma centers, examined the effects of 90 days of enteral or oral citicoline (2,000 mg) versus placebo initiated within 24 hours of injury in patients with complicated mild, moderate, and severe TBI.

The researchers found that the citicoline and placebo groups did not differ significantly at the 90-day evaluation on measures of cognitive and functional status. Rates of favorable improvement for the Glasgow Outcome Scale-Extended were 35.4% in the citicoline group and 35.6% in the placebo group. For all other scales, the rate of improvement ranged from 37.3% to 86.5% in the citicoline group and from 42.7% to 84% in the placebo group.

There was no significant treatment effect in the two severity subgroups (moderate/severe and complicated mild TBI). In patients with moderate/severe TBI, no statistically significant difference was observed between treatment groups at the 180-day evaluation.

The overall proportion of patients reporting serious adverse events was similar between the placebo and citicoline groups.

New Drug Investigated for Insomnia Relief

A new drug may bring help for individuals with insomnia, according to a study published in the online issue of Neurology.

The drug, suvorexant, blocks the chemical messengers in the brain called orexins, which regulate wakefulness. Other drugs for insomnia affect different brain receptors.

Taking the drug suvorexant increased the amount of time people spent asleep during the night, according to the study. The study involved 254 people ages 18 to 64 who were in good physical and mental health but had insomnia that was not due to another medical condition.

The participants took either the drug or a placebo for 4 weeks, then switched to the other treatment for another 4 weeks. The participants spent the night in a sleep laboratory with their sleep monitored on the first night with each treatment and then again in the fourth week of each treatment.

While taking the drug, participants’ sleep efficiency, which reflects the total amount of time they slept during a fixed, 8-hour time in bed, improved by 5% to 13% compared with those taking placebo. They also experienced 21 to 37 fewer minutes awake during the night after they had fallen asleep than those who took the placebo.

Drug manufacturer Merck has submitted a New Drug Application for the treatment with the U.S. Food and Drug Administration.