

Implanted device may detect, prevent epileptic seizures

by Bend Weekly News Sources

Oregon Health & Science University neurologists are studying an implanted, defibrillator-like device for the brain that may help people with medically uncontrolled epilepsy finally get relief from seizures. The Responsive Neurostimulator (RNS) system, manufactured by NeuroPace of Mountain View, Calif., is a battery-powered, microprocessor-controlled device programmed to detect abnormal electrical patterns created by epileptic activity. It can then respond with a short train of electrical pulses to the activity site that aborts the seizure. "It's a very sophisticated device. It's analogous to a pacemaker," said David Spencer, M.D., associate professor of neurology in the OHSU School of Medicine and co-director of the OHSU Comprehensive Epilepsy Center. "The device can recognize seizure onset very early and essentially respond to those electrical impulses before the seizure develops into a clinical seizure. It's a completely new approach to treating seizures." OHSU is one of 28 sites around the country conducting a two-year, double-blinded trial of the device's safety and effectiveness. The sites will recruit a total of 240 adult subjects ages 18 to 70 - 10 of them at OHSU - with disabling motor simple partial seizures, complex partial seizures or secondarily generalized seizures. Disabling seizures are those severe enough to cause injuries or significantly impair functional ability. Eligibility for the study is determined during a 12-week period in which potential study subjects are evaluated and asked to maintain a seizure diary. Qualified participants must average three or more disabling seizures a month for the three months and have failed treatment with at least two antiepileptic medications. They also must have no more than two brain regions identified in diagnostic testing as sites for epileptic activity. The RNS device, measuring 1.5 inches by 2.5 inches, is implanted on the brain in a space created by removing a piece of skull. It's attached to two leads, which may either be depth leads implanted deep in the brain at the site of epileptic activity, or cortical strip leads placed on the surface of the brain above the activity site.

"It's kind of space-age stuff. It's really cool," Spencer said. "Five years ago, this device was a cart with multiple machines on it. It was the size of a small refrigerator." After the four-hour surgery, participants are randomly split into two groups - one with the stimulator turned off and the other with the device turned on - and followed during a four-month blinded evaluation period. After the initial test period, all participants will have stimulation enabled. A preliminary study in January 2006 found that 62 people implanted with the RNS device experienced no device related serious adverse effects. Stimulation-related symptoms in several subjects were addressed by adjusting the stimulation settings. "Epilepsy is an abnormality of electrical activity in the brain, so it seems like an appropriate condition to treat with electrical stimulation," Spencer said. "We're fighting fire with fire." Halting seizures before they start would bring welcome relief to the estimated 2.7 million Americans suffering from active epilepsy. About 200,000 new cases of the neurological disorder are diagnosed each year, and its prevalence increases with age: It affects 326,000 children 14 and younger, and 570,000 people in the 65-and-older age group. Current treatments include medication, as well as vagus nerve stimulation, or VNS, which uses an implanted, battery-powered generator the size of a pocket watch to send 30-second electrical impulses to the left vagus nerve in the neck every five minutes through a wire implanted under the skin. VNS is a "much more nonspecific" therapy than RNS, and unlike the RNS device, it "doesn't respond to the seizure itself," Spencer said. Another therapy involves removing brain tissue at the site of epileptic activity. "But anytime you remove brain tissue, there's the potential for deficits or problems," he points out. RNS offers "a unique opportunity" for people with epilepsy, Spencer said. "We need new options that are innovative, and this has never been tried before. It's very gratifying when people with epilepsy become candidates for surgery that could eventually make them seizure-free."

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