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Clinical Trial to Treat Brain Tumors with Electric Fields

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(PhysOrg.com) -- The University of Illinois at Chicago is taking part in an international, multi-center study for patients newly diagnosed with the most common and aggressive type of brain tumor, glioblastoma multiforme, or GBM.

The clinical trial will evaluate the safety and efficacy of an investigational device that targets rapidly growing cancer cells with intermediate frequency electrical fields. Treatment with the device will be tested in combination with standard-of-care therapy and compared to standard-of-care therapy alone.

The Novo-TTF is a non-invasive medical device that disrupts the division of cancer cells in the brain using alternating electrical fields called "tumor-treating fields" delivered to the surface of the scalp by insulated electrodes.

Standard treatment includes surgical removal of the tumor, radiation and chemotherapy with an oral drug called temozolomide.

Dr. Herbert Engelhard, associate professor of neurosurgery and site investigator for the trial at UIC, said that in a pilot study, "early data suggest that this investigational treatment may increase the length of time before disease progression and increase median overall survival in newly diagnosed GBM patients."

"The concept is quite simple," he said. "The tumor-treating fields cause

the quickly growing cancer cells to die instead of dividing. And because brain tumor cells have different electrical properties than healthy cells, the healthy cells are spared from damage."

After a baseline MRI is used to determine the location of the tumor, physicians place several electrodes on the patient's shaved head. The electrodes are connected to the Novo-TTF medical device powered by a portable battery. The patient remains on the portable device for 22 hours a day, indefinitely, while continuing his or her daily activities.

Approximately five out of every 100,000 Americans are diagnosed each year with glioblastoma, according to the American Brain Tumor Association. Glioblastoma multiforme is the most deadly of all brain tumors. Standard therapy often does not provide a cure and causes side effects that diminish quality of life.

"Unfortunately, many patients with these aggressive brain tumors do not have many options," said Engelhard. "The goal is to provide new treatment options, improve survival and hopefully improve their quality of life."

While not considered a cure for the deadly brain tumor, the treatment may extend life for some people, said Engelhard. However, as the research is in its early stages, the benefit of Novo-TTF for patients with GBM has not yet been established.

The trial will enroll approximately 283 patients at 12 U.S. centers and nine centers in Europe. Two-thirds of the patients will receive continuous therapy with the NovoTTF-100A in addition to standard treatment; the other one-third will receive the standard treatment alone. All patients will be evaluated for disease progression.

UIC currently has three patients enrolled.

One patient, Gerald Bagnowski of Chicago, said that he continues his active lifestyle, which includes being a part-time elementary school gym teacher and an avid golfer, despite his diagnosis and treatment with the NovoTTF.

"To me, it was a life-or-death situation, and I felt the study was in my best interest," said Bagnowski, who is married and has three adult sons.

In 2006, in an earlier clinical trial for patients who had recurrent glioblastoma, UIC enrolled the first person in the U.S. who was randomly assigned to receive the novel NovoTTF therapy.

Today, 54-year-old Daniel Torres of Chicago has worn the device for 3 1/2 years.

Results of the previous clinical trial for patients with recurrent GBM have not yet been published.

Provided by University of Illinois at Chicago