Researchers to begin study of new radiation therapy system to treat breast cancer

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After more than a decade of research and development, researchers in the Department of Radiation Oncology at the University of Maryland School of Medicine will begin enrolling patients in the first clinical trial of GammaPod, a new high-precision, image-guided radiation therapy system specifically designed to treat early-stage breast cancer.

The GammaPod system, which uses thousands of precisely focused beams of radiation from 36 rotating sources in combination with a two-layer, vacuum-assisted cup that immobilizes the breast to achieve accuracy within 2 millimeters, was developed at the University of Maryland School of Medicine.

Seventeen patients will be enrolled in the study to evaluate clinical feasibility and safety - a necessary step in gaining approval from the U.S. Food and Drug Administration (FDA) to market the system. In July, the FDA granted GammaPod an exemption to use the technology for the first time in clinical research. The testing will take place at the University of Maryland Medical Center.

"GammaPod is the first system designed to treat early breast cancer with stereotactic precision which will allow for high-dose radiation therapy, otherwise known as stereotactic body radiotherapy, or SBRT. There's no other radiation-therapy delivery system like it in the world," says principal investigator Steven J. Feigenberg, MD, professor of radiation oncology at the University of Maryland School of Medicine and a radiation oncologist at the University of Maryland Marlene and Stewart

Greenebaum Cancer Center.

"This system represents a very sophisticated method to deliver highly targeted radiation directly to a breast tumor while minimizing damage to the remaining breast and major organs, such as heart and lungs," says Dr. Feigenberg, who is also director of clinical research and co-director of the Program of Excellence in Technology-Based Translational Research in the Department of Radiation Oncology.

Dr. Feigenberg says the study could begin as early as November once the Maryland Department of the Environment completes its approval process.

The results of this initial study will be submitted to the FDA, which will decide whether to grant the 510(k) application to market the device. If the application is approved, additional clinical trials to further test the technology will be conducted. Dr. Feigenberg leads a clinical consortium of four other medical centers in the United States and Canada where GammaPod will be available over the next year, and researchers at those sites are working together to develop clinical protocols.

Cedric X. Yu, MS, DSc, a clinical professor of radiation oncology at the University of Maryland School of Medicine, invented and developed the technology with the help of a $3.5 million Small Business Innovation Research (SBIR) grant from the National Institutes of Health. The technology was patented in 2006 with support from the University of Maryland, Baltimore's Office of Research and Development.

"With standard therapy, patients with early-stage breast cancer have surgery to remove the tumor, followed by five to seven weeks of radiation treatments to destroy any residual cancer cells," says Dr. Yu, now Chief Executive Officer of Xcision Medical Systems, maker of the GammaPod system. "We believe that GammaPod has the potential to

significantly shorten the treatment time to a few sessions over the course of a week, and in the future, potentially eliminate the need for surgery in select patients."

In the upcoming study, patients will receive a single "boost" treatment with GammaPod to the site where the tumor was removed, along with three to five weeks of traditional radiation treatments to the whole breast. The total radiation treatment regimen will be reduced by one week.

"Stereotactic radiotherapy is most commonly used to treat tumors in the brain and in other parts of the body, such as the lung, spine and liver. With GammaPod, we now have the ability to optimize the use of this technology for breast cancer and potentially enable a paradigm change in how we treat early-stage tumors with this new noninvasive option," says William F. Regine, MD, FACR, FACRO, the Isadore & Fannie Schneider Foxman Endowed Chair and professor of radiation oncology at the University of Maryland School of Medicine, chief of radiation oncology at the University of Maryland Medical Center and co-inventor of the GammaPod.

"The development of GammaPod represents the type of extraordinary innovation and entrepreneurial spirit that we foster through our faculty at the University of Maryland School of Medicine," says E. Albert Reece, MD, PhD, MBA, vice president for medical affairs at the University of Maryland and the John Z. and Akiko K. Bowers Distinguished Professor and dean of the School of Medicine. "Dr. Yu has invented other technologies now used in the field of radiation oncology and has dedicated his career to developing more effective treatments for patients."

With the GammaPod system, patients receive treatments while lying prone on a treatment couch. A two-layer, vacuum-assisted cup

immobilizes the patient's breast during imaging and treatment. The breast cups come in 28 sizes to provide a proper fit. The treatment will take from five minutes to 40 minutes, depending on the treatment plan, Dr. Yu says. "We wanted to make sure the treatment process is as comfortable for the patient as possible," he adds.

Dr. Yu holds 20 patents for advances in radiation oncology technology. He came to the University of Maryland School of Medicine in 1997 as director of medical physics in the Department of Radiation Oncology and was named Entrepreneur of the Year in 2010 by the University of Maryland, Baltimore, for his efforts to bring technology to patients.

Provided by University of Maryland