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UF awarded \$11.9 million for prostate cancer research comparing proton and X-ray therapies

GAINESVILLE, Fla. — A University of Florida research team has been approved for a five-year, \$11.9 million award to directly compare the potential benefits and harms of proton therapy to standard radiation therapy when treating prostate cancer.

Nancy Mendenhall, M.D., medical director of the UF Health Proton Therapy Institute, leads the team that received funding from the Patient-Centered Outcomes Research Institute, or PCORI, for a large-scale pragmatic clinical study on prostate cancer — the most common non-skin cancer afflicting men in the United States, according to the American Cancer Society.

There are around 160,000 new cases of prostate cancer diagnosed each year in the United States, and approximately one-third of all men with the disease receive radiation therapy as part of their treatment. However, this can cause short-term and long-term bowel and bladder damage that leads to organ dysfunction and significantly impacts the patient's quality of life. Most radiation therapy is delivered using X-rays, but proton therapy is an alternative that uses a focused beam of accelerated protons rather than traditional X-rays to target tumors and cancer cells more precisely.

The use of proton therapy in prostate cancer is controversial, however, because it is a more expensive treatment and its effects on patient quality of life, organ dysfunction and cancer cure rates relative to standard radiation treatment are unknown. Therefore, many insurers do not cover proton therapy for prostate cancer because of its high cost and the unanswered questions about its effectiveness compared to X-rays. The goal of the newly funded study is to find answers to these questions.

Mendenhall, also a professor and associate chair in the department of radiation oncology at UF, and Ronald Chen, M.D., an associate professor in the department of radiation oncology at the University of North Carolina at Chapel Hill, are the study's principal investigators.

“This is a critically important study that will compare outcomes between proton and conventional radiation in cohorts of 3,000 men with prostate cancer,” said Mendenhall. “It will determine whether there are differences in disease control, toxicity and quality of life in survivors —

providing much-needed answers to patients, families, medical teams, hospitals, insurers and policy makers.”

The study will compare 1,500 patients treated with proton therapy with 1,500 patients treated with standard radiation therapy from a total of 42 treatment centers across the United States. The study will collect information on patient-reported quality of life, physician-reported and patient-reported side effects, and prostate cancer recurrence. Some participants receiving proton therapy will also be randomly assigned to receive eight weeks of treatment at a lower intensity or four weeks at a higher intensity, to determine which regimen has a greater impact on cure rates and side effects.

“This large, multi-institutional PCORI-funded study led by Dr. Mendenhall represents a concrete opportunity to move the field of radiation oncology toward the best approaches to reducing suffering and curing this oftentimes devastating disease,” said Paul Okunieff, M.D., a professor and chair of the department of radiation oncology at UF.

Mendenhall’s team collaborated with several stakeholders to design this study, including patients, caregivers, prostate cancer advocacy groups, insurers and minority engagement groups — because, according to the American Cancer Society, the disease occurs more often in African-American men and in Caribbean men of African ancestry than in men of other races.

Mendenhall’s study was selected for funding through PCORI’s Pragmatic Clinical Studies Initiative, an effort to produce results that are broadly applicable to a diverse range of patients and care situations and can be more quickly taken up in routine clinical practice. It was one of 14 studies selected through a highly competitive review process in which patients, caregivers and other stakeholders joined scientists to evaluate the proposals.

“Dr. Mendenhall is a visionary clinician and research scientist who’s a driving force in this country in advocating for less-toxic radiation therapy,” said Jonathan Licht, M.D., director of the UF Health Cancer Center. “This is the type of leading-edge, pragmatic clinical study that we at the University of Florida want to be known for.”

PCORI is an independent, nonprofit organization authorized by Congress in 2010. Its mission is to fund research that provides patients, their caregivers and clinicians with the evidence-based information needed to make better-informed health care decisions. The UF award has been approved pending completion of a business and programmatic review by PCORI staff and issuance of a formal award contract.



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