

Official Title of the Study: Pilot study using multi-parametric magnetic resonance imaging for organ delineation and tumor response assessment of prostate cancer patients being treated with radiation therapy.

NCT number: NCT03180398

Date: July 13th, 2023

Statistical Plan

Sample size has been determined based upon the feasibility and low risk to patients, funding, and the consideration of the statistical power to measure detectable changes in endpoints. Patients will complete the Abbreviated EPIC questionnaire in writing, at home or in the clinic, per Radiation Therapy Oncology Group guidelines. Differences between pre-treatment and post-treatment MR Imaging/EPIC scores, age, race, education, body mass index, prostate volume, and cancer risk (based on prostate specific antigen, Gleason score, and T-stage). p-values < 0.05 will be considered statistically significant. Reported p-values are 2-sided. A clinically relevant change in HRQOL is defined as a difference from pretreatment to post-treatment that exceeds half of the standard deviation of the pre-treatment value.