

ACTIVE CLINICAL STUDY

Low and Intermediate Risk Prostate Cancer: Emulating HDR Brachytherapy Dosimetry

STUDY	Prospective Evaluation of CyberKnife® Radiosurgery of Low and Intermediate Risk Prostate Cancer: Emulating HDR Brachytherapy Dosimetry
PRINCIPAL INVESTIGATOR	Donald B. Fuller, M.D. (CyberKnife Centers of San Diego, San Diego, CA) Chad Lee, Ph.D. (CyberKnife Centers of San Diego, San Diego, CA)
SPONSOR	Accuray Incorporated
PRIMARY AIMS	<ol style="list-style-type: none">1. To determine clinical efficacy by monitoring biochemical disease-free survival (bDFS) over 5 years2. Using descriptive statistics to compare bDFS rates following CyberKnife treatment to published HDR monotherapy bDFS rates3. To assess acute and late gastrointestinal and genitourinary toxicities following CyberKnife treatment of prostate cancer in low and intermediate risk patients
SECONDARY AIMS	<ol style="list-style-type: none">1. To assess clinical response by monitoring rates of local failure, distant failure, clinical disease-free survival, disease-specific survival and overall-survival2. To assess quality of life in this population following treatment
PATIENT POPULATION	Early stage organ confined prostate cancer Low Risk: Stage T1b-T2a and Gleason 2-6 and PSA \leq 10 Intermediate Risk: Stage T2b and Gleason 2-6 and PSA \leq 10 Stage T1b-T2b and Gleason 2-6 and PSA \leq 20 Stage T1b-T2b and Gleason 7 and PSA \leq 10
METHODS	Primary treatment of organ confined prostate cancer by CyberKnife Radiosurgery 9.5 Gy x 4 fractions with an HDR dose distribution within the prostate
PARTICIPATING CENTERS	CyberKnife Centers of San Diego, San Diego, CA (PI) Participating sites TBD

For more information regarding potential patient enrollment, please contact Omar Dawood, MD, MPH, Vice President, Clinical Development at odawood@accuray.com or +1.408.789.4457.

