

ACTIVE CLINICAL STUDY

Low and Intermediate Risk Prostate Cancer: Homogeneous Dose Distribution

STUDY	Prospective Evaluation of CyberKnife® Radiosurgery of Low and Intermediate Risk Prostate Cancer: Homogeneous Dose Distribution
PRINCIPAL INVESTIGATOR	Robert Meier, M.D. (Swedish Medical Center, Seattle, WA) Cristian Cotrutz, Ph.D. (Swedish Medical Center, Seattle, WA) Martin Sanda, M.D. (Beth Israel Deaconess Medical Center, Boston, MA) Irving Kaplan, M.D. (Beth Israel Deaconess Medical Center, Boston, MA)
SPONSOR	Accuray Incorporated
PRIMARY AIMS	1. To assess acute and late gastrointestinal and genitourinary toxicities following CyberKnife® Stereotactic Radiosurgical treatment of prostate cancer in low and intermediate risk patients
SECONDARY AIMS	1. To assess clinical response rates by PSA monitoring, overall survival and disease-specific survival 2. To assess quality of life in this population following treatment 3. To assess economic implications of treatment with CyberKnife® Radiosurgery
PATIENT POPULATION	Early stage organ confined prostate cancer <u>Low Risk:</u> Stage T1b-T2a and Gleason 2-6 and PSA \leq 10 <u>Intermediate Risk:</u> 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 7.25 Gy x 5 fractions with a homogeneous dose distribution within the prostate
PARTICIPATING CENTERS	Swedish Cancer Center, Seattle, WA (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.

