iROCK

INTERNATIONAL RADIOSURGERY ONCOLOGY CONSORTIUM FOR KIDNEY

REGISTRY

Background & Rationale

The International Radiosurgery Oncology Consortium for Kidney (IROCK) was established in 2014 to harmonize treatment approaches and collaborate in research into stereotactic ablative radiotherapy (SABR) for primary renal cell carcinoma (RCC). Eight international institutions that had completed Phase I clinical trials and/or published clinical evidence in the field of SABR were invited to participate and compete a comprehensive survey to develop a practice consensus statement (Siva et al, Future Oncol. 2016 12(5): 637–45). Additional institutions have now joined IROCK, a retrospective, multi-institutional database has been established (Siva et al, Cancer, 2018;124:934-42) and five-year follow-up data was recently analysed (Siva et al, Lancet Oncol. 2022;23(12):1508-16). Establishing a prospective registry is the next phase of IROCKs research.

The purpose of the IROCK Registry is to establish efficacy and survival outcomes after SABR for primary RCC. IROCK registry data may also provide a better understanding of ablative radiobiology and response assessment techniques for the purpose of establishing functional imaging protocols (e.g., MRI or PET) that are more predictive of treatment outcome post-treatment biopsy or CT scans. We will also collect critical data to inform on renal function outcomes, and document novel combinations of systemic targeted agents and/or immunotherapies to establish their ability to enhance the effectiveness of the SABR technique.

Methods

The IROCK Registry is an international, multicenter, prospective, observational registry which will enroll patients with diagnosis of RCC and receiving kidney SABR. As a general guidance, departments with experience of treating 10 or more cases of RCC with SABR per annum are encouraged to express interest in participating in the IROCK Registry.

De-identified data will be extracted from patient's medical records and entered into a purpose built, secure, web-based (REDCap) database. Data from the IROCK Registry will not be available for analysis until the registry has been established for at least 3 years. A Data Management and Access plan has been developed.

Protocol Synopsis

Protocol Title	Stereotactic Ablative Radiotherapy (SABR) in Renal Cell Carcinoma (RCC): International Radiosurgery Oncology Consortium for Kidney (IROCK) Prospective Registry: "The IROCK Registry"
Target Disease	Primary renal cell carcinoma (RCC)
Primary Clinical Objective	To evaluate local failure rates with SABR
Secondary Objectives	1) To evaluate overall survival (OS) 2) To evaluate Progression-Free Survival (PFS) 3) To evaluate cancer-specific survival (CSS) 4) To evaluate distant failure rates 5) To evaluate variables predictive of outcomes after SABR 6) To evaluate renal function post-SABR 7) To evaluate SABR safety 8) To evaluate organ at risk (OAR) tolerances
Exploratory Objectives	To evaluate optimal radiological parameters for response assessment Additional exploratory objectives will be developed throughout the lifetime of the registry.
Study Design	An international, multicenter, prospective, observational registry which will enroll patients with diagnosis of RCC and receiving kidney SABR.
Trial Population	Adult patients who have undergone SABR for RCC who fulfil the inclusion criteria.
Primary Endpoint	Time to local failure: investigator defined progression guided by Response Evaluation Criteria in Solid Tumors (RECIST) definitions; • measured from the date of SABR treatment to the date of first evidence of local progression defined using RECIST version 1.0, or date of last follow-up, whichever occurs first. Distant progression and death will be considered censoring events
Follow up	Follow-up data will be collected every 6 months

Funding

The IROCK Registry has secured funding for five years (until 2026) via a generous donation from the Lo Foundation. Site payments comprise an initial AUD$400 per patient following baseline data completion, and AUD$50 per patient follow-up record.

Registry Governance

To ensure accountability of results produced by the IROCK Registry, a Steering Committee was established. The IROCK Registry Steering Committee acts as a Management Committee and an Independent Review Panel for applications to use registry resources (i.e. data). The Steering Committee are nominated representatives of Consortium investigators who will serve for a period of five years after which they may nominate for re-election.