

EA8211/SOAR

For Patients with Advanced Renal Carcinoma

EA8211 Available Through ECOG-ACRIN Cancer Research Group

Phase III Randomized Trial of Stereotactic Ablative Radiotherapy (SAbR)
for Oligometastatic Advanced Renal Carcinoma (**SOAR**)

Patient Population

See Section 3 for Complete Eligibility Details

- Age \geq 18 years, ECOG PS 0-2
- Must have a pathologically (histologically or cytologically) proven diagnosis of renal cell carcinoma (RCC)
 - ◊ May have any RCC histology except a histology that has a sarcomatoid component
- Must have primary site addressed by local therapy; if the primary RCC is intact, the patient must undergo local treatment to the primary before randomization
- Must not have brain metastases
- Must have favorable/intermediate International Metastatic RCC Database Consortium (IMDC) risk (0-2); refer to Appendix III for modified IMDC risk categories
- Must have a total of 2-5 metastatic lesions (RECIST)
- Must have documentation from a radiation oncologist confirming all sites are amenable to SAbR
- May have received prior therapy in the adjuvant setting
 - ◊ Otherwise, must not have received any prior systemic therapy for metastatic RCC
- Must not have metastasis involving these locations: ultra-central (within 2cm of carina) lung, invading GI tract (i.e., esophagus, stomach, intestines, colon, rectum), skin, and scalp
- Must not have severe, active comorbidity defined per protocol
- Patients with known history/current symptoms of cardiac disease, or history of treatment with cardiotoxic agents should be NYHA class 2B or better
- Must have adequate organ and bone marrow function per the recommended guidelines and the respective FDA package insert
- Patients with HIV, HBV, or HCV are eligible per protocol
- In order to participate in the QOL portion of EA8211, the patient must speak English or Spanish

Treatment Plan

See Section 5 for Complete Treatment Details

- Patients on both arms will receive standard FDA-approved first line systemic therapy (options defined per protocol; selection at the discretion of the treating physician [may not be changed once chosen])
- **Arm A:** Sequential SAbR followed by first line systemic therapy at progression on SAbR
 - ◊ All sites of measurable metastasis will be treated with SAbR (sites are defined per protocol); patients developing metastases following the initial round of SAbR will get additional SAbR for up to a total of 6 sites
 - ◊ The initial round of SAbR should be completed within 8 weeks of randomization
 - ◊ Interfractional interval must be no less than 36 hours and no greater than 8 days; treatment duration is defined per metastatic site treated with SAbR
 - ◊ Patients progressing on SAbR should begin standard of care systemic therapy within 4 weeks of progression event
 - ◊ *Note: Centers must satisfy a set of minimum technology requirements as well as use appropriate modalities for treatment*
- **Arm B:** First line systemic therapy (refer to the protocol for guidance on clear cell vs. non-clear cell histology)
 - ◊ These patients can have standard palliative/prophylactic radiation therapy with 3D-CRT and non-IMRT planning as needed

Study Chair:

Raquibul Hannan, MD, PhD

Study Co-Chair:

Suzanne Cole, MD

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) <https://open.ctsu.org/open>

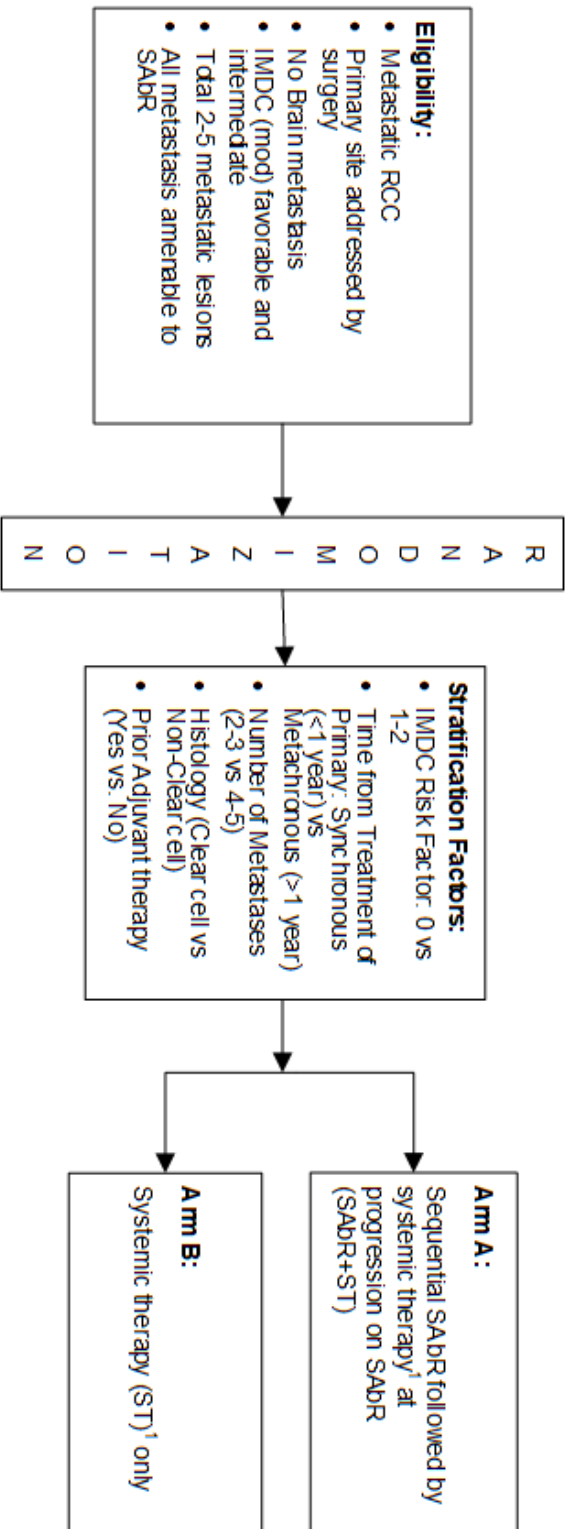
Protocol Information

ECOG-ACRIN Operations-Boston: 857-504-2900, <http://ecog-acrin.org> (Member Login)

Please Enroll Your Eligible Patients!

EA8211

Schema



Accrual Goal = 472

Cycle Length = assessments will be done every 3 months

1. Systemic therapy will consist of standard FDA approved first line systemic therapy for renal cell carcinoma, as per NCCN guidelines and with the options outlined in Section 5.1.2. The selection of the systemic therapy regimen used is at the discretion of the treating physician and in agreement with the patient. Once the regimen has been declared and started, patients may not switch to another regimen option.