NCI Community Oncology Research Program

EAQ191/CARISMA

For Patients with Renal Cell or Thyroid Cancer

EAQ191 Available Through ECOG-ACRIN Cancer Research Group

Cancer Therapy Risk-Reduction with Intensive Systolic BP Management (CARISMA)- A Phase II Study

Patient Population

See Section 3.0 for Complete Eligibility Details

- Age ≥ 18 years; English speaking; ECOG PS 0-2; must have access to internet
- Must have renal cell cancer or thyroid cancer initiating treatment with anti-angiogenic tyrosine kinase inhibitors (AA-TKIs) including: sunitinib, sorafenib, pazopanib, cabozantinib, lenvatinib, vandetanib, or axitinib
  - ◊ Alternative medications can be considered for patients with allergic reactions/with pre-existing medications that may interact with the proposed BP medications (see protocol)
  - ◊ Registration does not need to occur before initiation of AA-TKI, but must occur within 6 weeks following AA-TKI start date
- Prior exposure to another AA-TKI or concurrent/ prior treatment with immunotherapy is permissible
- Must have systolic BP ≥ 130 mmHg on 2 or more occasions according to any in-clinic visit in the 12 weeks prior to or during the initial 4 weeks of treatment with an AA-TKI
  - ◊ Patients with a prior diagnosis of hypertension/ on pre-existing anti-hypertensive medications are eligible with a diagnosis of hypertension alone, but must not be on more than 3 baseline BP medications with SBP ≥ 160 mmHg
- Must agree to comply with performing home blood pressure monitoring using an Omron7250 oscillometric monitor (or equivalent, per protocol)
- Must not have a kidney transplant, end-stage renal failure on dialysis, or history of repeated hyperkalemia per protocol
- Must not have certain heart issues per protocol
- Must not have brain surgery or brain radiotherapy within 2 weeks prior to registration
- Patients with HBV, HCV, or brain metastases are eligible per protocol

Treatment Plan

See Section 5.0 for Complete Treatment Details

The unit of randomization will be the institution

Arm A– Intervention (Intensive SBP Control; Goal SBP <120 mmHg):

- Patients will receive care from a team comprised of a clinical pharmacist and a blood pressure specialist who will collaborate with the patient and their physicians
  - ◊ Coordination of medications, lifestyle interventions, and frequent contact with the patient
- Maintenance phase: patients will be trained to measure BP 4x in 1 day (am and pm; 2 measurements taken each time) every 2 weeks
- Titration phase: A SBP > 120 results in medication titration (see protocol Appendix IV)
  - ◊ If the SBP > 150 mmHg, 2 sequential steps (i.e., 2 medications) can be combined. Fixed-combination drug products can be used to decrease pill burden; when patients are already receiving drugs, the regimen should be tailored accordingly
  - ◊ BP monitoring 3 consecutive days every 2 weeks (4x in 1 day; am and pm; 2 measurements each time)

Arm B– Non-intervention (Standard Care; Goal SBP <140mmHg):

- Patients will be given the BP monitor with a list of standard recommendations for lifestyle
- Home BP readings once every 2 weeks (am and pm; 2 measurements each time; 4x in 1 day)
- There will be NO titration phase/monitoring of BP in a titration phase
  - ◊ Anti-hypersensitive treatment is at the discretion of the treating provider

Study Chair:
Bonnie Ky, MD, MSCE

Co-Chair:
Kenneth Margulies, MD

Patient Enrollment

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

Protocol Information

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

Please Enroll Your Eligible Patients!

EAQ191

ECOG-ACRIN cancer research group

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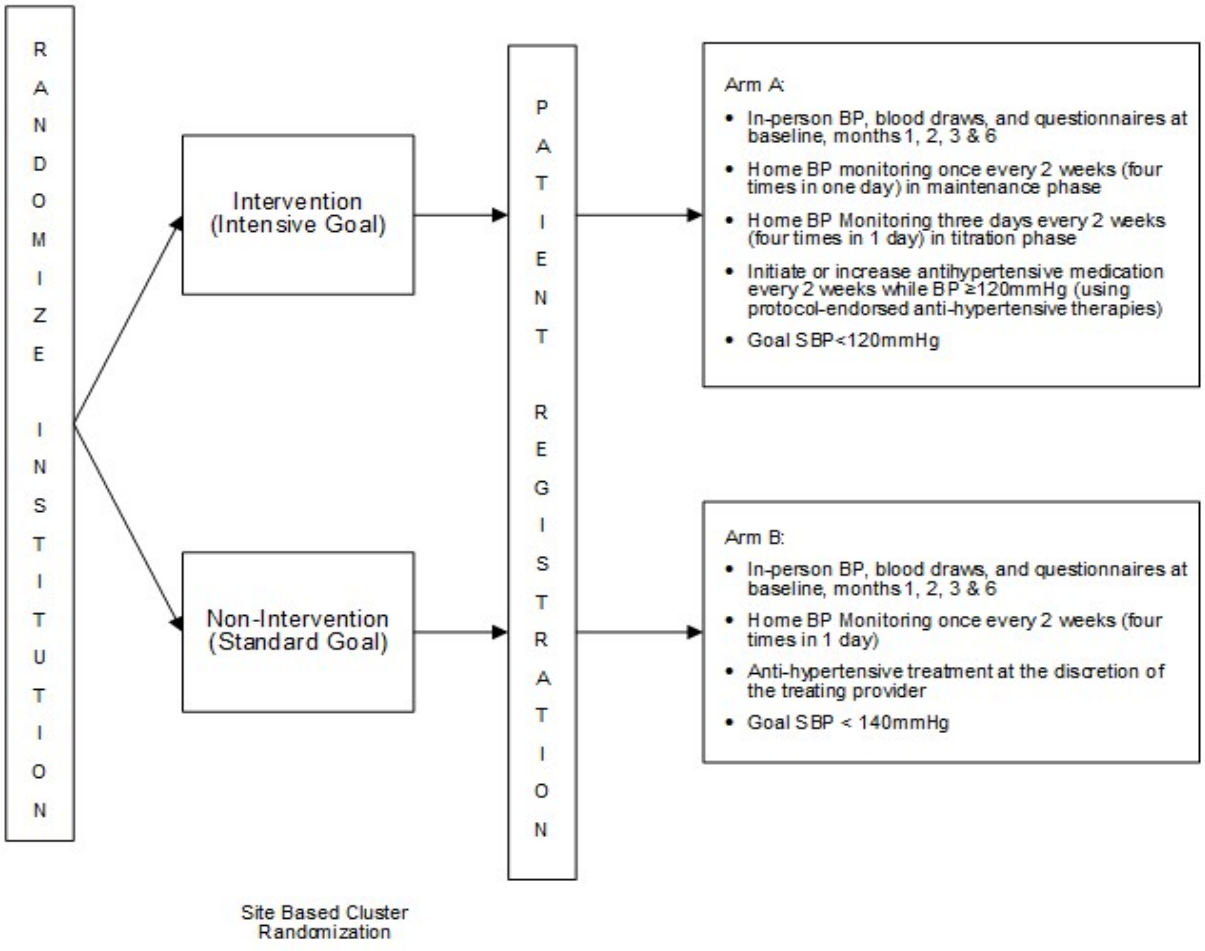
Schema



Site Based Cluster Randomization