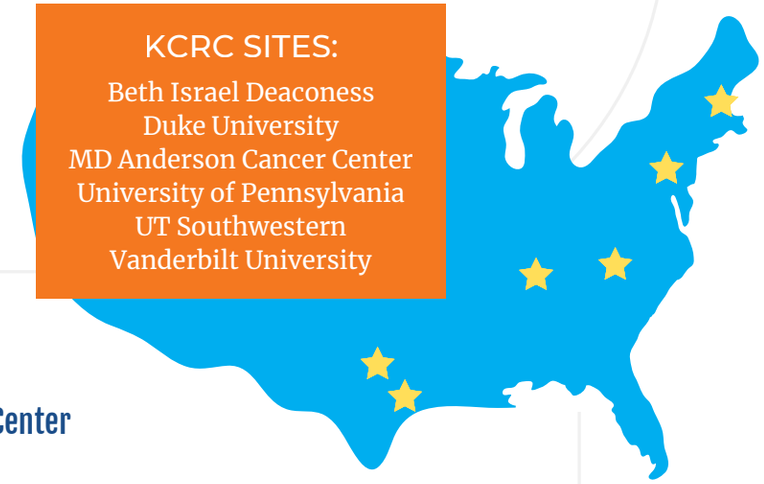
KCRC Kidney Cancer RESEARCH CONSORTIUM

A Randomized Phase 2 Trial of Nivolumab, Relatlimab, plus Ipilimumab vs. Nivolumab plus Ipilimumab in first-line advanced renal cell carcinoma (RCC)

WILL ENROLL
60patients

at

KCRC SITES:
Beth Israel Deaconess
Duke University
MD Anderson Cancer Center
University of Pennsylvania
UT Southwestern
Vanderbilt University



Initiating Site:
Vanderbilt University Medical Center
Dr. Brian Rini

Summary: The study's goal is to determine if the combination of relatlimab, nivolumab, and ipilimumab is more effective than nivolumab and ipilimumab at controlling advanced renal cell carcinoma.

Treatment with nivo/ipi as a combination is FDA-approved. Rela is not FDA-approved for treating RCC. The combination of nivo/ipi/rela is investigational. Receiving treatment on the study drugs may help control the patient's disease. The patient may receive no benefit from treatment. Future patients may benefit from the information learned in this study.

Trial Schema

60 eligible patients,
randomized 2:1 into two arms:

N = 40	N = 20
nivolumab 480mg IV Q4W + relatlimab 160mg IV Q4W + ipilimumab 1mg/kg IV Q8W	nivolumab 480mg IV Q3W + ipilimumab 1mg/kg IV Q3W x 4 doses, then Q4W

Primary Endpoints:
- Safety of nivolumab, relatlimab, and ipilimulab as determined through assessment of trial-limiting toxicities (TOX)
- Objective response (OR) to nivolumab, relatlimab, and ipilimumab by Response Evaluation Criteria in Solid Tumors v1.1 (RECIST 1.1).

Secondary Endpoints:
- PFS, duration of response (DOR), rate of primary PD, treatment-free survival, and rate of irAEs of nivolumab, relatlimab, and ipilimumab

Key Criteria

- Advanced Clear Cell Renal Cell Carcinoma
- No Prior Treatment
- Karnofsky performance status greater than or equal to 70%
- Measurable disease per RECIST1.1

WOCBP: Women Of Child-Bearing Potential must not be pregnant and must utilize two forms of contraception while on treatment and for 23 weeks after treatment.

Men who are sexually active with WOCBP must agree to utilize acceptable contraception while on treatment and for 31 weeks after.

Drug Frequency: Patients in nivo/ipi arm will get nivo/ipi every 3 weeks for 4 visits; after, nivo every 4 weeks. Patients in nivo/ipi/rela arm will get nivo/rela every 4 weeks and ipi every 8 weeks.

Costs: Patients in nivo/ipi arm will have nivo/ipi billed to patient insurance. Patients in nivo/ipi/rela arm will have nivo/rela covered by the study and ipi billed to patient insurance.

Clinic Visit Frequency: Patients in nivo/ipi arm will have first 4 visits every 3 weeks; after, every 4 weeks. Patients in nivo/ipi/rela arm will have visits every 4 weeks.