A Phase 3 Randomized Study Comparing PERioperative Nivolumab vs. Observation in Patients with Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)

Can the addition of perioperative nivolumab increase recurrence-free survival?

Key Eligibility
- Patients with >7 cm tumor, or any size tumor with invasion into vein/fat (T3), or TanyN+ planned to have partial or radical nephrectomy
- Patients can have oligometastatic RCC if can be resected/ablated at same time or within 12 weeks of nephrectomy
- Patients may have bilateral renal masses, as long as the contralateral tumor is treated within 12 weeks

Key Interventions
- Patients will either be randomized to receive perioperative nivolumab or observation
- Partial or radical nephrectomy does not need to be completed at center where research treatment (nivolumab) given

Please see schema on next page.

If you are interested in offering your patients access to this study and are not already in touch with a treatment center about this study, please contact us!

STUDY CONTACT INFORMATION: EA8143_PROSPER@ecog-acrin.org
Key Eligibility Criteria

- No clinical/radiological evidence of distant metastases (M0) unless the M1 disease can be resected/definitely treated (limited to 3 metastases; no brain, liver, or bone metastases permitted)
- Biopsy required if randomized to nivolumab if no prior histological confirmation of RCC within 12 months prior to Step 0
- No prior systemic anti-cancer therapy for the current RCC
- No prior history of RCC that was resected with curative intent within the past 5 years; no other current malignancies requiring active treatment; limitations on active/known suspected autoimmune disease

## Study Schema

- Potential patient identified in urology clinic and referred to medical oncologist
- Biopsy required
- Biopsy not required
- Partial/Radical Nephrectomy
- Observation
- Partial or Radical Nephrectomy
- Nivolumab x 1 dose
- Nivolumab x 9 doses
- Nivo x 9 doses q 4 wks (starting 4–10 weeks post op)
- Clear cell or Non-clear cell ≥T2, Nany, M0 or oligo M1
- Patient returns to urology clinic for surgery
- Patient continues on study with medical oncologist

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Watch Experts Discuss the PROSPER RCC Trial