

PD-INHIBITOR (NIVOLUMAB) AND IPILIMUMAB FOLLOWED BY NIVOLUMAB VS. VEGF TKI CABOZANTINIB WITH NIVOLUMAB: A PHASE III TRIAL IN METASTATIC UNTREATED RENAL CELL CANCER [PDIGREE]

Eligibility Criteria (see Section 3.0)

Step 1 Registration Criteria

- Histologic documentation of renal cell carcinoma with clear cell component
- Metastatic disease
- Measurable disease
- Intermediate or poor risk per IDMC criteria
- CNS disease is allowed, if stable
- Karnofsky PS \geq 70%
- Prior Treatment per Section 3.2.6
- Non-pregnant and non-nursing
- Age \geq 18 years
- None of the conditions in Section 3.2.9

Required Initial Laboratory Values

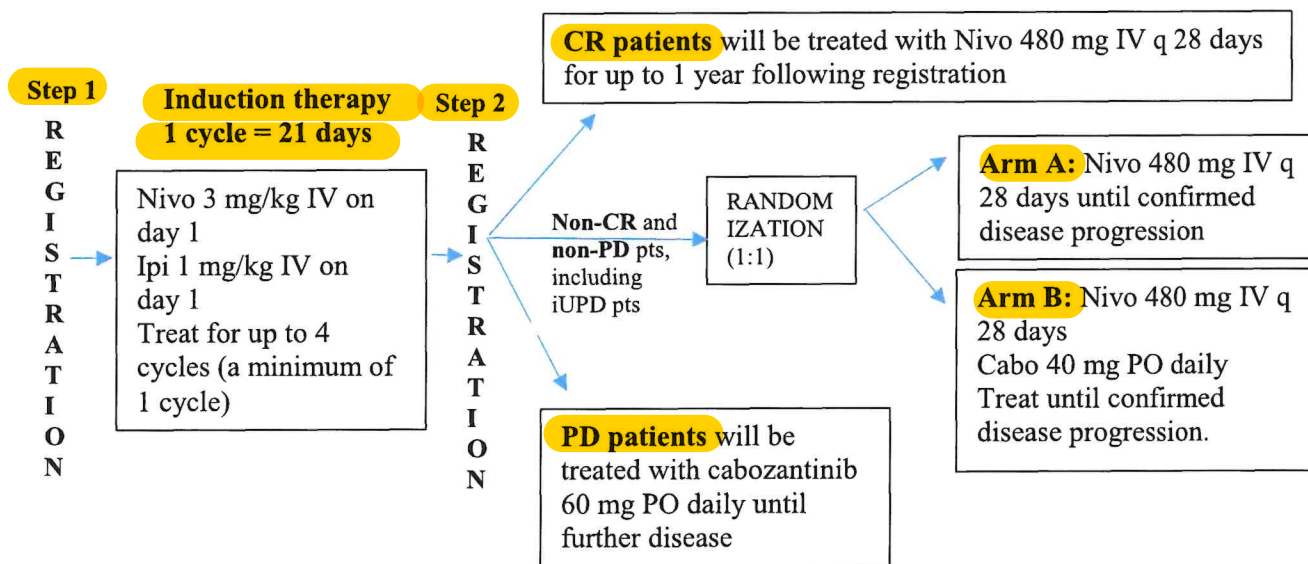
- Absolute neutrophil count (ANC): \geq 1500/mm³
- Platelet count: \geq 100,000/mm³
- Hemoglobin: \geq 8 g/d
- Calc. creatinine clearance: \geq 30 mL/min
- Urine protein \leq 1+ or UPC Ratio $<$ 1
- Total bilirubin: \leq 1.5 x ULN (except patients with Gilbert's, see Section 3.2.10)
- AST/ALT: \leq 2.5 x ULN or $<$ 5 x ULN if hepatic

Step 2 Registration Criteria

- Must have completed at least 1 cycle of ipi/nivo
- All AEs have resolved to \leq grade 1
- \leq 80 days from last dose of ipi/nivo

Schema

1 cycle = 28 days



Patients with a complete response at 1 year following registration will discontinue treatment. Patients will be followed for 5 years or until death, whichever comes first.

Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.