Article details

Title of article
The future of perioperative therapy in advanced RCC: how can we PROSPER?

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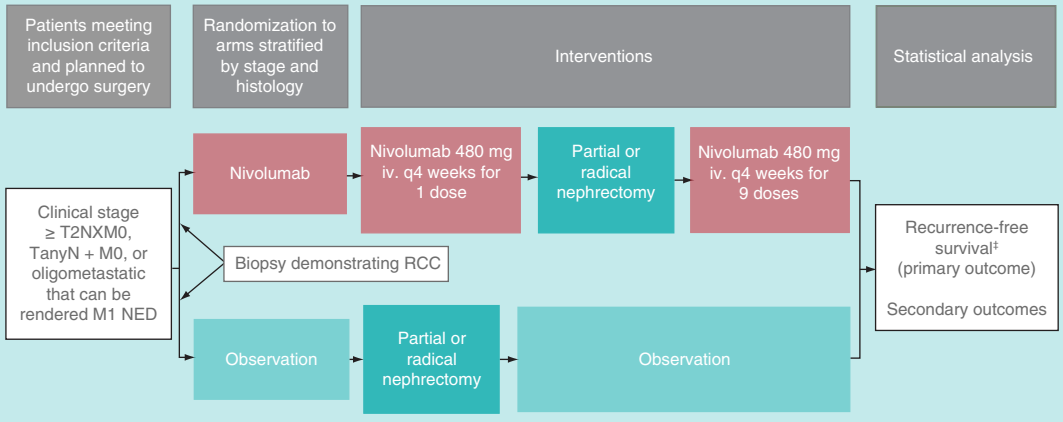
Trial registration number
NCT03055013

Study design and treatment including planned sample size, planned study period and study procedures



805 Planned sample size: 805

Planned study period: 02/02/2017 to completion of enrollment

Follow-up: All patients will undergo routine clinical post-operative surveillance with cross-sectional imaging at 20 and 40 weeks after randomization followed by every 6 months through year 3 and then annually from years 4 - 10. Imaging studies will be banked to allow for potential blinded central review if deemed necessary and for future correlative studies

Primary objectives/rationale

Primary objective
Improve recurrence free survival for patients with high-risk or oligometastatic RCC

Secondary objectives
Increase overall survival and quality of life, ensure safety and tolerability, pursue correlative studies

Key eligibility criteria

18+ Age ≥18 years

Serum lab value cutoff requirements within 4 weeks of randomization (e.g. WBC, absolute granulocyte count, platelets, hemoglobin, creatinine, bilirubin, AST, ALT)

ECOG 0 or 1

Clinical stage ≥T2NX or TanyN+ kidney tumor allowing for oligometastatic disease (≤3 metastases if planned to undergo local treatment within 12 weeks of nephrectomy)

Preoperative biopsy demonstrating RCC if randomized to nivolumab

Planned to undergo radical or partial nephrectomy

Glossary

ALT: Alanine transaminase; AST: Aspartate transaminase; ECOG: Eastern Cooperative Oncology Group; RCC: Renal cell carcinoma; RFS: Recurrence-free survival; WBC: White blood cell count

Outcome measures/end points

Primary end point
RFS at 5-years

Secondary end points
OS for entire cohort, RFS and OS for clear cell RCC subset