# National PROspective infrastructure for Renal Cell Carcinoma

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To set up a prospective, nationwide infrastructure that identifies and follows patients diagnosed with RCC and mRCC over time. This infrastructure will:• evaluate oncological and functional outcomes for patients diagnosed with RCC;• evaluate the...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Renal and urinary tract neoplasms malignant and unspecified |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON56090

**Source**
ToetsingOnline

**Brief title**
PRO-RCC

### Condition

- Renal and urinary tract neoplasms malignant and unspecified

**Synonym**
kidney cancer, renal cell carcinoma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Stichting PRO-RCC
**Source(s) of monetary or material Support:** Bristol-Myers Squibb,Ipsen Pharmaceuticals,Merck Sharp & Dohme (MSD),Pro-RCC

## Intervention

**Keyword:** cohort, Kidney cancer, Prospective, RCC

## Outcome measures

### Primary outcome

This efficient and unique infrastructure for RCC research creates a facility, that will yield detailed insights in RCC disease aspects and treatment in the Netherlands and enable improved patient accrual in clinical trials. Ultimately, this will lead to an introduction of improved new treatment options in daily clinical practice. Furthermore, the collected data on HRQoL, symptoms and clinical management from diagnosis to death will result in robust *real-world* patient data. Data from patients who undergo registered and experimental therapies can be studied to answer relevant questions on relapse and progression to invasive or metastatic disease, and on optimal (sequencing of) treatment regimens and HRQoL as part of the decision making.

### Secondary outcome

n/a

# Study description

### Background summary

Survival after a renal cell cancer (RCC) diagnosis strongly depends on local tumor extent, lymph node involvement and the presence of distant metastases. However, there remains high inter-patient variability regarding clinical treatment outcome and there is hardly knowledge about impact on health-related quality of life (HRQoL). The clinical outcome is likely to be influenced by a combination of biochemical factors, histopathological features, genomic profile, environmental factors and other clinical factors, independent from tumor stage. However, it is still unclear which, how, and to what extent these

factors influence tumor recurrence and mortality in both early stage (I-III) RCC and late stage (IV) mRCC in the general population.
As a result of rapid technical developments, a range of new minimally invasive treatment options for RCC have entered the clinic. These interventions aim for optimal local control with less damage to surrounding tissue, faster recovery and less side effects. However, most of these interventions have not been thoroughly evaluated in trials yet. Besides, many new medicines for the treatment of RCC have recently become available. The impact of these systemic treatments on HRQoL and symptoms in the general population during active treatment and thereafter remains unclear. Therefore it is highly desirable to validate results from clinical trials on treatment outcomes in real-world data. Unfortunately, the current documentation of patients treated in general practice is insufficient to provide comparable patient cohorts in terms of prognostic characteristics, treatment parameters and patient-reported outcome measures (PROMs). Also, there is an increased availability of molecular markers with potential prognostic and/or predictive value. Validation of such markers requires large numbers of patients, far more than the number of patients participating in clinical trials.
Altogether, a prospective observational cohort combining PROMS and clinical data provides the opportunity to fill these gaps. Our cohort will result in a dataset that reliably represents the real-world situation of both localized and metastatic RCC patients. This data will be highly informative for guiding patients and health care professionals in the choice of treatment and will improve the communication between patient and health care professional. Moreover, this project will allow the design and execution of Trials within a Cohort, the so-called TWICs or cohort multiple randomized controlled trials (cmRCT). So, the existing infrastructure of the cohort will improve possibilities for research among RCC patients.

## Study objective

To set up a prospective, nationwide infrastructure that identifies and follows patients diagnosed with RCC and mRCC over time. This infrastructure will:
• evaluate oncological and functional outcomes for patients diagnosed with RCC;
• evaluate the impact of RCC treatment on the following PROMS: HRQoL, symptoms, work ability, nutrition;
• evaluate patient-experienced quality of care measures (PREMS);
• inform on the landscape of RCC in the Netherlands and evolving changes in treatment;
• validate the (cost- )efficacy and safety of novel diagnostic and therapeutic approaches in a real-world patient population; • facilitate selection of eligible patients for future intervention studies, thereby improving accrual;
• yield historical and concurrent control groups fur future single arm intervention studies;

## Study design

All patients diagnosed with histologically proven RCC are eligible for PRO-RCC. The infrastructure is embedded in the logistic framework of PROFILES and the Netherlands Cancer Registry (NCR). PROMS will be collected longitudinally through online questionnaires. Clinical data will be collected in a uniform manner by trained independent data managers of the NCR.

**Study burden and risks**

n/a

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

• Histologically proven RCC or mRCC or high clinical suspicion
• Age >= 18 years at time of inclusion
• Written informed consent
• Able to read and understand the patient information

### Exclusion criteria

None

## Study design

### Design

**Study type:** Observational non invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 19-01-2023 |
| Enrollment: | 10000 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 21-01-2022 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 25-05-2023 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

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| Approved WMO Date: | 01-09-2023 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 01-11-2023 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 13-06-2024 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 08-11-2024 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL79186.018.21 |