

A prospective study of primary metastatic renal cell carcinoma treated with immunecheckpoint inhibitors and cytoreductive nephrectomy vs primary tumour in place

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The aim of this study is to investigate whether performing a cytoreductive nephrectomy has a beneficial effect on overall survival in patients with metastatic renal cancer receiving systemic therapy using immunocheckpoint inhibitors.

Ethical review	Approved WMO
Status	Pending
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON57224

Source

ToetsingOnline

Brief title

PrimerX

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Renal disorders (excl nephropathies)
- Renal and urinary tract therapeutic procedures

Synonym

Renal Cell Carcinoma, renal malignancy

Research involving

Human

Sponsors and support

Primary sponsor: Oncologie

Source(s) of monetary or material Support: Ministerie van OC&W,iknl

Intervention

Keyword: Cytoreductive Nephrectomy, Immunecheckpoint inhibitors, Renal Cell Carcinoma

Outcome measures

Primary outcome

Overall survival

Secondary outcome

complications after cytoreductive nephrectomy

Study description

Background summary

In past years, much research has been done into the beneficial effects of cytoreductive nephrectomy in patients with metastatic renal cancer receiving systemic therapy with positive results. In the meantime systemic therapy, and in particular immunotherapy, have changed. Patients with metastatic renal cancer are increasingly treated with immunecheckpoint inhibitors, but the effect of adding cytoreductive nephrectomy in this group of patients has not yet been investigated.

Study objective

The aim of this study is to investigate whether performing a cytoreductive nephrectomy has a beneficial effect on overall survival in patients with metastatic renal cancer receiving systemic therapy using immunecheckpoint inhibitors.

Study design

A randomized controlled trial. All eligible patients have already been enrolled in the PRO-RCC registry, a registry that collects prospective observational

data, and have also given consent to be included in other studies as a control cohort. This design is called a TWiC (trial within cohort). After randomization, patients who are randomized into the therapy arm will receive a patient information via their treating physician. Upon participation, an informed consent will be signed and the patient will be scheduled for surgery.

Intervention

Cytoreductive nephrectomy

Study burden and risks

extent of the burden for patient in the control arm: not applicable

extend of the burden for patient in the therapy arm: admission (+- 3 days) and surgery (cytoreductive nephrectomy) as life-prolonging therapy

Contacts

Public

Selecteer

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Histologically confirmed diagnosis of metastatic renal cell carcinoma of intermediate to poor risk treated with immunecheckpoint inhibitors

Exclusion criteria

NA

Study design

Design

Study type: Interventional
Intervention model: Parallel
Allocation: Randomized controlled trial
Masking: Open (masking not used)

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-05-2023
Enrollment: 750
Type: Anticipated

Ethics review

Approved WMO
Date: 14-03-2024
Application type: First submission
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	NL83948.018.23