Comparison of Real-World Outcomes of 2nd Targeted Therapies in Patients with Metastatic Renal Cell Carcinoma (mRCC) – a Multi-Country Retrospective Chart Review

Gepubliceerd: 16-11-2015 Laatst bijgewerkt: 18-08-2022

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23232

Bron
NTR

Aandoening

Oncology- Metastatic renal cell carcinoma (mRCC)

Ondersteuning

Primaire sponsor: Novartis
Overige ondersteuning: Company sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Characterize differences in the following outcomes in mRCC patients receiving 2nd targeted therapy with everolimus, sorafenib, or axitinib following a 1st targeted therapy with sunitinib

or pazopanib:

a. OS from the initiation of 2nd targeted therapy
b. Treatment duration of the 2nd targeted therapy
c. PFS from the initiation of 2nd targeted therapy

Toelichting onderzoek

Achtergrond van het onderzoek

Renal Cell Carcinoma (RCC) is a common adult malignancy worldwide. At RCC diagnosis, more than one fourth of patients present with metastatic disease, and about half of those with resectable disease eventually develop metastases. Tyrosine kinase inhibitors (TKIs) and inhibitors of the mammalian target of rapamycin (mTOR) are the current standard of care for patients with metastatic RCC (mRCC). To date, four TKIs (axitinib, sorafenib, sunitinib, and pazopanib) and two inhibitors of mTOR (temsirolimus and everolimus) have been approved for the treatment of mRCC in multiple countries, including the EU 5, Japan, Canada, and US.

TKIs can prolong overall and progression-free survival in patients with mRCC, and have been the most commonly used as 1st targeted therapy. However, almost all RCC patients eventually fail their 1st targeted therapy and experience progression. Maximizing the value of the mRCC therapeutic armamentarium will require careful selection of the next treatment. Given the growing number of treatment options, limited comparative evidence and lack of consensus on proper sequencing in mRCC, a well-conducted observational study of real-world outcomes of 2nd targeted therapy may provide valuable inputs for decision making. Commonly used 2nd targeted therapies include sorafenib, everolimus, axitinib, and temsirolimus (Market share data, Novartis data on file). In addition, an increased use of axitinib and a decreased use of temsirolimus have been observed (Market Share data on file). Thus, the current study proposes to evaluate the real-world use of everolimus, sorafenib and axitinib as 2nd targeted therapy.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

N/A as we are not assigning patients into a specific treatment group

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Adult patients (age ≥18 years, males and females) diagnosed with mRCC per medical chart

• The patient received 1st targeted therapy with either sunitinib or pazopanib (i.e. a TKI other than sorafenib or axitinib)

• The patient experienced disease progression during their 1st targeted therapy and subsequently initiated one of the following 2nd targeted therapies:

(1) Everolimus

(2) Sorafenib

(3) Axitinib

• The date of initiating 2nd targeted therapy was during a defined time period from the time when everolimus, sorafenib, and axitinib all became available in the local market, to 20 months (tentative, pending on sample size) prior to the data extraction time

• Treatment history and outcomes related to mRCC are available for chart review

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• The patient used an mTOR inhibitor, bevacizumab or cytokines [IL-2, IFN- α2a] prior to initiation of the 2nd targeted therapy

• The patient used a combination therapy with ≥2 targeted agents prior to or upon the initiation of the 2nd targeted therapy

• The patient initiated the 2nd targeted therapy in an interventional trial in the mRCC setting

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	20-10-2015
Aantal proefpersonen:	450
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5560
NTR-old	NTR5681
Ander register	: 06-12-2014

Resultaten