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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23232

Source
NTR

Health condition

Oncology- Metastatic renal cell carcinoma (mRCC)

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Company sponsor

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Characterize differences in the primary outcomes within subgroups stratified by the following groups:

a. Type of 1st targeted therapy used

b. Long/short duration of 1st targeted therapy

Describe real-world treatment patterns:

a. Treatment duration of targeted therapies (by lines of treatment), and reasons for discontinuation

b. Dose, dose adjustment and underlying reasons for dose adjustment during 2nd targeted therapy; estimated total dose received for the 2nd-targeted therapy

c. Utilization and types of 3rd targeted therapies

Characterize differences in resource use following initiation of 2nd targeted therapy

Study description

Background summary

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.

Study design

N/A

Intervention

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

Contacts

Public
Woolgate Exchange

Dony Patel
25 Basinghall Street

London EC2V 5HA
United Kingdom
+44 (0)20 7 015 2388 / +44 (0)7760 158 663
Scientific
Woolgate Exchange

Dony Patel
25 Basinghall Street

London EC2V 5HA
United Kingdom
+44 (0)20 7 015 2388 / +44 (0)7760 158 663

Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-10-2015
Enrollment:	450
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5560
NTR-old	NTR5681
Other	: 06-12-2014

Study results