A Prospective Observational study to describe the pattern and effectiveness of the utilization of different treatment options for Metastatic Renal Cell Carcinoma

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Main Information

Primary registry identifying number
LBCTR2020074518

Protocol number
OPERA2020

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
10/07/2020

Primary sponsor
General Research Grant

Primary sponsor: Country of origin
United Arab Emirates

Date of registration in primary registry
11/11/2021

Date of registration in national regulatory agency
10/07/2020

Public title
A Prospective Observational study to describe the pattern and effectiveness of the utilization of different treatment options for Metastatic Renal Cell Carcinoma

Acronym
OPERA

Scientific title
A Prospective Observational study to describe the pattern and effectiveness of the utilization of different treatment options for Metastatic Renal Cell Carcinoma

Acronym
OPERA

Brief summary of the study: English

Background and objective: Renal cell carcinoma (RCC), the eighth most common malignancy affecting adults, accounts for around 4% of new cancer cases in the United States. It is the seventh most common cancer in men and the ninth most common in women. The targeted therapies with Tyrosine Kinase inhibitors (TKI) and immune -based treatments are important components of treatment for advanced kidney cancer. This study will be conducted to describe the pattern of use of TKI and/or immunotherapy treatment options whether as monotherapy or in combination regimen and to assess the potency of the therapy sequence in routine clinical practice.
Methods: This is a regional, multicenter observational prospective study, to gather routine clinical practice data on the usage patterns and outcomes of immunotherapy and/or TKI, for metastatic RCC. One hundred eighty-five patients diagnosed with metastatic renal cell carcinoma and will be on immunotherapy and/or TKI in this observational study will be enrolled over three years.
Assessment: Efficacy parameters include response to treatment, duration of progression-free survival, duration of overall survival, partial response, time to response, Karnofski Performance Status, and tumor assessment. Safety parameters will include laboratory data, ECG, adverse events, and serious adverse events as pruritus, diarrhea, and organ toxicity as liver, lungs, kidneys, thyroid, and neurologic. Data will be recorded at different at baseline, during treatment at 3, 6,12, and 36 months, and at every follow-up once yearly after the last administration of immunotherapy and TKI until the last follow-up.

Brief summary of the study: Arabic

الخلفية والهدف: سرطان الخلايا الكلوية (RCC) : يمثل حوالي 4٪ من حالات الأورام الخبيثة شيوعًا التي تصيب البالغين ، وهو سابع أكثر أنواع السرطان شيوعًا بين الرجال والتاسع الأكثر شيوعًا بين النساء. تعد العلاجات المستهدفة باستخدام مثبطات التيروزين كيناز (TKI) و العلاجات القائمة على المناعة مكونات مهمة لعلاج سرطان الكلى المتقدم. سيتم إجراء هذه الدراسة لوصف نمط استخدام TKI و / أو خيارات العلاج المناعي سواء كعلاج وحيد أو في نظام مشترك لتقييم فعالية تسلسل العلاج في الممارسة السريرية الروتينية.
الطرق: هذه دراسة استطلاعية رصدية إقليمية متعددة المراكز لجمع بيانات الممارسة السريرية الروتينية حول أنماط ونتائج استخدام العلاج المناعي و / أو TKI لـ سرطان الخلايا الكلوية المنتشر. مائة وخمسة وثمانون مريضا تم تشخيصهم بسرطان الخلايا الكلوية المنتشر ويخضعون للعلاج المناعي و / أو TKI في هذه الدراسة المستقبلية سيتم تسجيلهم على مدى ثلاث سنوات.
التقييم: تشمل معلمات الفعالية الاستجابة للعلاج ، ومدة البقاء على قيد الحياة الخالية من التقدم ، ومدة البقاء الكلي ، والاستجابة الجزئية ، ووقت الاستجابة ، وحالة أداء Karnofski ، والأحداث السلبية ، وتخطيط القلب ، والأحداث السلبية ، وتقييم الورم. تشمل معايير الأمان بيانات المختبر ، الخطيرة مثل الحكة ، والإسهال ، وتسمم الأعضاء مثل الكبد والرئتين والكلى والغدة الدرقية والعصبية. سيتم تسجيل البيانات بشكل مختلف عند خط الأساس ، وأثناء العلاج في TKI حتى آخر 3 و 6 و 12 و 36 شهرًا ، وفي كل متابعة مرة واحدة سنويًا بعد آخر إدارة للعلاج المناعي و متابعة.

Health conditions/problem studied: Specify

Patients with:

-histologically confirmed metastatic renal cell cancer
-treated by immunotherapy and/or TKI

Interventions: Specify

Any immunotherapy and TKI prescribed for the management of mRCC as per FDA/EMA approval

Key inclusion and exclusion criteria: Inclusion criteria

-Patients ≥ 18 years old
-Histologically confirmed metastatic renal cell cancer
-Patients treated by immunotherapy and/or TKI
-Signed informed consent form obtained prior to study entry only for living patients

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

80

Key inclusion and exclusion criteria: Exclusion criteria

-History of another malignancy within the past 5 years except cured basal cell carcinoma of the skin or excised carcinoma in situ of the cervix
-Pregnancy
-Current participation in another clinical trial

Type of study
Observational

Type of intervention
N/A

Type of intervention: Specify type
N/A

Trial scope
N/A

Trial scope: Specify scope
N/A

Study design: Allocation
N/A

Study design: Masking
N/A

Study design: Control
N/A

Study phase
N/A

Study design: Purpose
N/A

Study design: Specify purpose
N/A

Study design: Assignment
N/A

Study design: Specify assignment
N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

Therapeutic indication

Therapeutic benefit

Study model
Case-Only

Study model: Explain model
Pure observational study

Study model: Specify model
N/A

Time perspective
Prospective

Time perspective: Explain time perspective
-First Patient in: 01 July 2021
-Last Patient in: 01 January 2024
-Last Patient out: 01 January 2025
-Estimated enrolment duration: 2.5 years
-Estimated follow-up duration: Until death, loss to follow-up or study termination.
-Database lock planned date: 30 March 2025

Time perspective: Specify perspective
N/A

Target follow-up duration

Target follow-up duration: Unit

12

months

Number of groups/cohorts

4

Biospecimen retention

Samples without DNA

Biospecimen description

Metastatic Cell Carcinoma

Target sample size

185

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

01/07/2021

Date of study closure: Type

Anticipated

Date of study closure: Date

01/01/2025

Recruitment status

Recruiting

Recruitment status: Specify

Date of completion

30/03/2025

IPD sharing statement plan

No

IPD sharing statement description

Summary Results Reporting

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
NA	NA

Sources of Monetary or Material Support

Name
NA

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Marwan Ghosn	Hotel Dieu	Lebanon	01613395	marwan.ghosn@usj.edu.lb	Principle Investigator
Scientific	Marwan Ghosn	Hotel Dieu	Lebanon	01613395	marwan.ghosn@usj.edu.lb	Principle Investigator

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu de France, Beirut	Prof. Marwan Ghosn	Oncology/ Hematology	Approved
Hammoud Hospital University Medical Center, Saida	Prof. Fadi Farhat	Oncology/ Hematology	NA
Sheikh Khalifa Specialty Hospital (SKSH)-Ras al Khaimah	Dr. Hassan Jaafar	Oncology/ Hematology	NA
King Faisal Specialty Hospital- Jeddah	Prof. Jamal Zekri	Medical Oncology	NA
King Saud bin Abdul Aziz -Jeddah	Prof. Mubarak Mansour	Medical Oncology	NA
Kuwait Cancer Control Center	Dr. Ehab Abdou	Medical Oncology	NA
King Hussein Cancer Center - KHCC	Dr. Samer Salah	Medical Oncology	NA
Cairo University Hospitals	Prof. Emad Hamada	Medical Oncology	NA
Kasr Al Aini Hospital	Prof. Hamdy Abdel Azim	Medical Oncology	NA

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	30/06/2020	Nancy Alam	nancy.alam@usj.edu.lb	01421229
Hotel Dieu de France	31/05/2021	Nancy Alam	nancy.alam@usj.edu.lb	01421229

Countries of Recruitment

Name
Lebanon
Saudi Arabia
United Arab Emirates
Egypt
Kuwait
Jordan

Health Conditions or Problems Studied

Condition	Code	Keyword
renal cell carcinoma	Carcinoma in situ of other specified sites (D09.7)	renal cell carcinoma

Interventions

Intervention	Description	Keyword
Immunotherapy and/or TKI	This is a regional, multicenter observational prospective study, to obtain routine clinical practice data on the usage patterns and outcomes (safety and effectiveness) of immunotherapy and/or TKI, for metastatic renal cell carcinoma in real-life practice	Immunotherapy and/or TKI

Primary Outcomes

Name	Time Points	Measure
To describe the efficacy of immunotherapy and/or TKI alone for the treatment of metastatic renal cell carcinoma in terms of progression-free survival (PFS) and overall survival (OS)	one and three years	Progression-free survival and duration of overall survival
Assess the potency of the sequence therapy in terms of first, second, and third line therapy with the current real-world clinical practice	one and three years	Overall response rate, time to response and tumor assessment

Key Secondary Outcomes

Name	Time Points	Measure
To describe the safety and toxicity profile of immunotherapy and/or TKI for fatigue, rash, nausea, pruritus and diarrhea and organ toxicity as liver, lungs, kidneys, thyroid and neurologic	one, three, six, twelve, and 36 months post treatment, and at 1st relapse	Lab data, ECG, Adverse events and serious adverse events
To compare patients' profile if the therapy is administered as first, second, or third line treatment options at one, three, six, twelve, and 36 months post treatment, and at 1st relapse	one, three, six, twelve, and 36 months post treatment, and at 1st relapse	Serious Adverse Events as pruritus, diarrhea and organ toxicity as liver, lungs, kidneys, thyroid and neurologic examination

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files