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Clinical evaluation of a urinary biomarker for the early detection of clear cell renal carcinoma

Submission date 22/01/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 06/02/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 25/11/2025	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Kidney cancer (KC) is the third most common type of tumor in the urinary system for both men and women and sadly, it's also one of the top causes of cancer-related deaths. Right now, there's no reliable test to catch KC early. This study aims to change that by looking into whether a substance called Perilipin-1 in your urine could be a good sign that you might have KC, no matter what stage the cancer is at. In simpler terms, this study is trying to find a urine test that could help catch KC earlier than it is right now.

Who can participate?
Patients with KC and healthy controls aged 18 years old and over

What does the study involve?
The present study is an analytical, case-control, prospective study that considers two groups:
Cases: patients who have been diagnosed with KC at any stage who are going to undergo one of the following:
1. Surgical treatment (partial or radical nephrectomy).
2. Systemic treatment for KC with histological confirmation of renal cancer by percutaneous biopsy
Controls: healthy volunteers who undergo a preventive check-up where an image (ultrasound, CT, or MRI) excludes renal masses (benign or malignant).

Urine creatinine and PLIN-1 will be measured in urine samples at baseline (cases and controls) and six months after surgery (only for cases). The urine sample will be obtained from voided urine, except for the baseline sample of patients undergoing nephrectomy, which will be obtained by bladder catheterization on the day of surgery.

What are the possible benefits and risks of participating?
Participants will not receive any experimental therapy, and there will be no cost to participate in the study. Finding a urinary marker that allows population screening will permit early diagnosis of KC, which will imply a better oncological outcome.
No risks provided at the time of registration.

Where is the study run from?
Instituto de Ciencias e Innovación en Medicina (ICIM) (Santiago, Chile)
Centro de Medicina Regenerativa
Clinica Alemana (Santiago, Chile)

When is the study starting and how long is it expected to run for?
April 2023 to December 2026

Who is funding the study?
Clinica Alemana (Santiago, Chile)
Universidad del Desarrollo

Who is the main contact?
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Additional identifiers

Protocol serial number
ID 1201

Study information

Scientific Title
Evaluation of urinary perilipin-1 (PLIN-1) as a Diagnostic biomarker in patients with clear renal cancer

Acronym
TOREADOR

Study objectives
Urinary Perilipin-1 is a valid diagnostic biomarker of kidney cancer in all its stages.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/04/2023, Comité Etico Científico de la Facultad de Medicina Clínica Alemana de Santiago-Universidad Del Desarrollo (Avda. La Plaza 680, Las Condes, Santiago, 7610658, Chile; None provided; ceccasudd@udd.cl), ref: 2023-25

Primary study design
Observational

Study design

Analytical case-control prospective study

Study type(s)
Diagnostic, Screening

Health condition(s) or problem(s) studied
Screening in patients with kidney cancer

Interventions
This is an analytical, case-control, prospective study that involves two experimental groups:
a) Cases: patients diagnosed with kidney cancer who are going to undergo nephrectomy (partial or radical). A urine sample (30 mL) will be obtained from a Folley catheter at the beginning of the kidney surgery. Additionally, a voided urine sample (30 mL) will be collected six months after surgery.
b) Controls: healthy volunteers. A voided urine sample (30 mL) will be collected at the inclusion in the study.

Intervention Type
Other

Primary outcome(s)
1. Creatinine (mg/dL) in urine samples measured with the modified JAFFE method, using the CREATININE DMSO kit (Applied Clinical Chemistry. S.A, Amposta, Spain) at baseline (cases and controls) and at six months after surgery (only for cases)
2. Perilipin-1 (PLIN-1) (ng/dL) in urine samples measured with a Sandwich ELISA assay using Human PLIN1/Perilipin Sandwich ELISA kit at baseline (cases and controls) and at six months after surgery (only for cases)

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Cases:
1. Patients ≥ 18-yr, male or female
2. Diagnosed with kidney cancer at any stage
3. Who are willing to undergo one of the following:
3.1. Surgical treatment (partial or radical nephrectomy).
3.2. Systemic treatment for kidney cancer with histological confirmation of renal cancer by percutaneous biopsy

Controls:
1. Healthy volunteers, ≥18-yr old, male or female
2. Who undergo a preventive check-up where an image (ultrasound, CT or MRI) excludes renal masses (benign or malignant)

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
150 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Cases:
1. Personal history of kidney surgery (for benign or malignant disease).
2. Current or recent treatment (<6 months) with chemotherapy, immunotherapy, or immune checkpoint inhibitors.
3. Clinical diagnosis of kidney cancer without histological confirmation

Controls:
1. Study in progress for possible kidney cancer
2. Personal history of kidney surgery, both for benign and malignant pathology
3. Current or recent treatment (<6 months) with chemotherapy, immunotherapy, or immune checkpoint inhibitors

Date of first enrolment
18/05/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Chile

Study participating centre
Centro de Medicina Regenerativa, Instituto de Ciencias e Innovación en Medicina (ICIM)
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Sponsor information

Organisation
Clínica Alemana

ROR
https://ror.org/028ynny55

Organisation
Universidad del Desarrollo

ROR
https://ror.org/05y33vv83

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Clínica Alemana de Santiago

Alternative Name(s)
Clínica Alemana

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (www.redcap.alemana.cl)

IPD sharing plan summary

Stored in non-publicly available repository