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Can a protein found in urine, called perilipin-1, be used as a marker to diagnose kidney cancer?

Submission date
22/01/2024

Recruitment status
Recruiting

Registration date
06/02/2024

Overall study status
Ongoing

Last Edited
06/02/2024

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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?
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)

Who is the main contact?
Dr Hugo Otaola, hotaola@alemana.cl

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Hugo Otaola Arca

ORCID ID
http://orcid.org/0000-0003-4952-2283

Contact details
Las Hualtatas 5099, depto 203, Vitacura
Santiago
Chile
7630352
+56 941089452
hotaola@alemana.cl

Type(s)
Public

Contact name
Dr Hugo Otaola Arca

Contact details
Las Hualtatas 5099, depto 203, Vitacura
Santiago
Chile
7630352
+56 941089452
hugotaolarca@hotmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ID 1201

Study information

Scientific Title
EvaluaTion Of urinaRy pErilipin-1 As a Diagnostic biOmarker in patients with kidney 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

Study design
Analytical case-control prospective study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Diagnostic, Screening

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/04/2023

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
150 Years

Sex
Both

Target number of participants
110

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
Clínica Alemana Santiago
Av Vitacura 5951, VItacura, Región metropolitana
Santiago
Chile
7650568

Sponsor information

Organisation
Clínica Alemana

Sponsor details
Av Vitacura 5951
Santiago
Chile
7650568
+56 222101111
clinicaalemana@alemana.cl

Sponsor type
Hospital/treatment centre

Website
https://www.clinicaalemana.cl/

ROR
https://ror.org/028ynny55

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

Publication and dissemination plan
Presentation of results at national and international conferences and publication in high-impact peer-reviewed journal

Intention to publish date
01/06/2027

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