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# Use of 64CuCl2 in urologic tumors

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| **Submission date**<br>15/11/2017 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>21/11/2017 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>21/11/2017 | **Condition category**<br>Cancer | [_] Individual participant data<br>[_] Record updated in last year |

**Plain English summary of protocol**

Background and study aims
The currently available imaging techniques are not accurate enough to evaluate the presence of small metastases in patients with tumours of the kidney, bladder, penis and prostate. The aim of this study is to find out how the images obtained from a PET/CT scan with a new tracer “drug” (64CuCl2) compare with the actual tumours removed during surgery.

Who can participate?
Patients aged over 18 with tumours of the kidney, bladder, penis and prostate who are about to undergo surgery

What does the study involve?
Participants undergo a special PET/CT scan with 64CuCl2. The images are compared with the tumours that are removed during surgery.

What are the possible benefits and risks of participating?
The special PET/CT scan may allow a better evaluation of the whole body with a single exam. The risks are minimal and are related to the use of 64CuCl2, but previous studies have not found any side effects.

Where is the study run from?
Santo Spirito Hospital (Italy)

When is the study starting and how long is it expected to run for?
January 2018 to December 2018

Who is funding the study?
Spirito Santo Hospital (Italy)

Who is the main contact?
Dr Manlio Mascia

## Contact information

**Type(s)**

Scientific

### Contact name
Dr Manlio Mascia

### Contact details
Via Istonia, 1/c
Cupello
Italy
66051

## Additional identifiers

### Clinical Trials Information System (CTIS)
2017-000490-17

### Protocol serial number
2.0

## Study information

### Scientific Title
Phase IIa clinical study of 64CuCl2: efficacy and safety of a new tracer for urologic tumors

### Study objectives
The aim of this study is to evaluate the diagnostic performance, the safety profile and the effectiveness of a new tracer (64CuCl2) for PET/CT scan exams in patients affected by urological tumors such as kidney, bladder, prostate and penis tumors.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Interventional prospective single-center Phase IIa trial

### Primary study design
Interventional

### Study type(s)
Diagnostic

### Health condition(s) or problem(s) studied
Urologic tumors (kidney, prostate, bladder, penis)

### Interventions
A comparison between nuclear imaging (PET/CT scan) pictures and surgical pathology in patients with different neoplasms undergoing surgical excision.

### Intervention Type
Procedure/Surgery

### Primary outcome(s)
Sensitivity and specificity based on whole body PET/CT after 64CuCL2 in primitive and metastatic lesions, measured immediately (1-2 days) after the PET/CT scan

### Key secondary outcome(s))
64CuCL2 PET/CT technique performance in target/background contrast (T/B), measured immediately (1-2 days) after the PET/CT scan

### Completion date
31/12/2018

## Eligibility

### Key inclusion criteria
1. Subject aged over 18 at diagnosis
2. Subject with renal or bladder or prostate or penile cancer waiting for surgical excision or imaging restaging due to progressive disease
3. Availability of already done cross-sectional imaging in the last month
4. Karnofsky index >80%
5. Absence of relevant comorbidities (see exclusion criteria)
6. Full mental ability to understand the value and the relevance of the protocol and the related procedures showed in the “Informativa per il soggetto”
7. Full mental ability in order to give informed consent
8. Negative pregnancy test for women potentially at risk for pregnancies

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Hb levels < 10 gr/dL
2. Presence of copper metabolism diseases (Menkes or Wilson diseases)
3. Previous participation in clinical trial involving ionizing radiation for diagnostic or therapeutic finality in the last year
4. Working exposition to ionizing radiation

5. Each condition that could alter and reduce the compliance of the subject to the participation to the study protocol
6. Mental inability to fully understand the “Informativa per il soggetto”

**Date of first enrolment**
03/03/2018

**Date of final enrolment**
03/07/2018

# Locations

**Countries of recruitment**
Italy

**Study participating centre**
**Santo Spirito Hospital, Nuclear Medicine Unit**
Via Fonte Romana, 8
Pescara
Italy
66124

# Sponsor information

**Organisation**
Ospedale Civile "Spirito Santo"

**ROR**
https://ror.org/01jj26143

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Spirito Santo Hospital, Pescara (Italy)

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

## IPD sharing plan summary

Other

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |