

Use of $^{64}\text{CuCl}_2$ in urologic tumors

Submission date 15/11/2017	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 21/11/2017	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 21/11/2017	Condition category Cancer	☐ Individual participant data ☐ 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” ($^{64}\text{CuCl}_2$) 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 $^{64}\text{CuCl}_2$. 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 $^{64}\text{CuCl}_2$, 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 $^{64}\text{CuCl}_2$: 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 ($^{64}\text{CuCl}_2$) 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

Primary study design

Interventional

Study design

Interventional prospective single-center Phase IIa trial

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 $^{64}\text{CuCL}_2$ in primitive and metastatic lesions, measured immediately (1-2 days) after the PET/CT scan

Key secondary outcome(s)

$^{64}\text{CuCL}_2$ 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