Use of 64CuCl2 in urologic tumors

Submission date 15/11/2017	Recruitment status No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 21/11/2017	Overall study status Completed	Statistical analysis planResults
Last Edited 21/11/2017	Condition category Cancer	Individual participant dataRecord 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

EudraCT/CTIS number 2017-000490-17

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design Non randomised study

Study setting(s) Hospital

Study type(s)

Diagnostic

Participant information sheet

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2018

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants 25

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"

Sponsor details

Via Fonte Romana,8 Pescara Italy 66124

Sponsor type Hospital/treatment centre

ROR https://ror.org/01jj26143

Funder(s)

Funder type Hospital/treatment centre

Funder Name Spirito Santo Hospital, Pescara (Italy)

Results and Publications

Publication and dissemination plan

After the collection and the analysis of the results at least one paper will be sent to a peer reviewed international journal after the overall trial end date.

Intention to publish date

31/12/2019

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