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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 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” (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
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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