Distribution, dosimetry and imaging of [195mPt]cisplatin in cancer patients

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Investigate the distribution, dosimetry and image quality of [195mPt]cisplatin in cancer patients

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON55147

Source
ToetsingOnline

Brief title
[195mPt]cisplatin imaging

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
lung cancer, Non-small-cell lung carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Kansen voor West

Intervention

Keyword: 195mPt, cisplatin, imaging, platinum

Outcome measures

Primary outcome

- Image quality: amongst others tumour-to-background ratio and visual assessment

- Dosimetry

Secondary outcome

- eGFR

- Treatment outcome according to MTB/physician decision.

Study description

Background summary

There is a great interpatient variability in response with cisplatin treatment and nephrotoxicity often occurs. [195mPt]cisplatin can provide useful information about the distribution and tumour/organ uptake of cisplatin. This information may be valuable for personalized medicine, for example for individualized treatment selection. Most recent studies with [195mPt]cisplatin have been performed on healthy subjects. However, cisplatin is used in patients with solid tumours and the biodistribution of cisplatin in the tumour is unknown and unmeasurable in healthy subjects. Other prior studies who investigated [195mPt]cisplatin on a very small scale in humans used outdated imaging equipment with suboptimal quantification. We now aim to explore evaluation of the biodistribution of cisplatin in this relevant patient group using modern imaging equipment.

Study objective

Investigate the distribution, dosimetry and image quality of [195mPt]cisplatin in cancer patients

Study design

Pilot/proof of concept study

Study burden and risks

[195mPt]cisplatin can provide useful information about the distribution and

tumour/organ uptake of cisplatin. In the future, this information can be used to optimize treatment with cisplatin for the individual patient. This study does not directly benefit the subjects included in this study, but their treatment is according to standard of care. Study patients will already be present in het AVL for their regular treatment every day. On the first day of the study, the patient needs to stay longer in the AVL because 2 SPECT/CTs and planar scans will be acquired. On the other study days, no or little time extra is needed to conduct the study.

The radiation burden of a single intravenous administration of 100 MBq [195mPt]cisplatin will be approximately 20 mSv (1). A low dose CT causes a radiation burden of 4 mSv. Altogether, the radiation burden for the first study patient will be 44 mSv (20 + 6 low dose CTs *4). For comparison, one diagnostic CT abdomen and thorax is 20 mSv.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- > 18 years of age.
- Diagnosed with NSCLC.
- Planned for concurrent radiotherapy with cisplatin.
- At least one pulmonary tumour lesion of at least 3 cm over the longest axis.

Exclusion criteria

- Not able to provide informed consent.
- Pregnant or breastfeeding.
- Previous treatment with platinum compounds.
- Claustrophobia.
- eGFR < 60 ml/min.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2022
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[195mPt]cisplatin
Generic name:	[195mPt]cisplatin

Ethics review

Approved WMO Date:	28-01-2022
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2020-002861-32-NL
CCMO	NL74272.031.21