Feasibility study to image [11C]docetaxel kinetics in patients with advanced solid tumors using PET-CT

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1. To develop and validate an optimal tracer kinetic model for quantitative analysis of [11C]docetaxel PET studies 2. To study the metabolism of [11C]docetaxel, to compare venous versus arterial sampling and to compare the use of an on-line...

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON31382

Source
ToetsingOnline

Brief title
[11C]docetaxel kinetics in patients in advanced cancer

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
advanced solid tumors

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Cancer Center Amsterdam

Intervention

Keyword: [11C]docetaxel, advanced solid tumor, PET-CT, pharmacokinetics

Outcome measures

Primary outcome

Pharmacokinetics of [11C]docetaxel

Secondary outcome

1. Comparison venous versus arterial sampling and comparison of an on-line

plasma curve with an IDIF

2. Reproducibility of [11C]docetaxel PET measurements

3. Biodistribution of [11C]docetaxel.

Study description

Background summary

Docetaxel is an important cytostatic agent used for the treatment of several types of cancer such as breast, lung and prostate cancer and is given either as single agent or in combination therapy. Unfortunately, the response rate of docetaxel is not 100%. In breast cancer for example, docetaxel usually has a response rate of about 50%, which results in unnecessary exposure to docetaxel and a delay of a more effective treatment in these patients. It is suggested that different pharmacokinetics may be involved according to differences in response. Ideally, responders should be selected from non-responders before initiating docetaxel treatment. A PET scan using a tracer dose of [11C]docetaxel may be useful to predict response of docetaxel therapy in cancer patients. Furthermore, [11C]docetaxel may be a valuable tool to investigate the effects of combination therapy (for example with trastuzumab or bevacizumab) on the uptake of docetaxel in cancer. A feasibility study to image [11C]docetaxel kinetics in patients with advanced cancer is the first step to evaluate [11C]docetaxel as tracer for PET imaging.

Study objective

1. To develop and validate an optimal tracer kinetic model for quantitative analysis of [11C]docetaxel PET studies

2. To study the metabolism of [11C]docetaxel, to compare venous versus arterial sampling and to compare the use of an on-line measurement plasma curve with an image derived input function (IDIF)

3. To define test-retest reproducibility of [11C]docetaxel-PET measurements

4. To study the biodistribution of a tracer dose of [11C]docetaxel in patients with advanced solid tumors.

Objectives can be addressed with a single study in 10 evaluable patients.

Study design

An observational study with invasive measurements.

Study burden and risks

This study with[11C]docetaxel is only justified in population of patients with advanced solid tumors who are planned to receive chemotherapy. There is only a little chance for injury. The arterial and venous cannula can cause a hematoma. During PET-CT scanning a maximum of 250 ml blood will be taken.
A PET-CT is a regular diagnostic imaging technique. The whole body radiation after intravenous injection of 370 MBq [11C]docetaxel is 2X2 mSv.
In addition a low dose CT scan performed during PET scanning has a radioactivity dose of 1-3 mSv. The total amount of radiation burden will be between 6 and 10 mSv during the entire study. To compare, every person living in the Netherlands receives a the radioactivity dose from the universe and the environment of 2-2,5 mSv per year.

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

- Patient age of 18-70 years
- Patients with advanced cancer planned to receive chemotherapy
- Life expectancy of at least 12 weeks
- Disease with a malignant lesion of at least 1,5 cm diameter within the chest as measured by Response Evaluation Criteria in Solid Tumors (RECIST)
- Performance status Karnofsky index > 60 %
- Hemoglobin > 6.0 mmol/l
- Written informed consent

Exclusion criteria

- Previous treatment with taxanes
- Claustrophobia
- Pregnant or lactating patients
- Patients having metal implants (e.g. pacemakers)
- Due to the fact that docetaxel is a substrate for P-glycoprotein (P-gp), patients using P-gp drugs like digoxin, cyclosporin, amiodarone, steroids, quinidine, colchicine, etoposide, anti-estrogens will be excluded
- Use of coumarin derivatives or inhibitors of thrombocyte aggregation
- Concurrent treatment with experimental drugs
- Participation in a clinical trial with any investigational drug within 30 days prior to study entry

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL17159.029.07