Prediction of tumour uptake of therapeutic docetaxel using [11C]docetaxel and PET-CT

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1) To study whether [11C]docetaxel uptake by tumours predicts tumour uptake of therapeutic docetaxel.2) To study the effects of therapeutic docetaxel on venous metabolite fractions of [11C]docetaxel.3) To study the relation between tumour blood flow…

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

Summary

ID

NL-OMON33256

Source
ToetsingOnline

Brief title
Effect of therapeutic docetaxel on [11C]docetaxel uptake in tumours

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
advanced solid tumour

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, docetaxel, oncology, PET-CT

Outcome measures

Primary outcome

Change in [11C]docetaxel uptake by tumours after administration of therapeutic docetaxel.

Secondary outcome

1) Change in venous metabolite fractions of [11C]docetaxel after administration of therapeutic docetaxel.

2) The relation between [11C]docetaxel uptake and blood flow in tumours after administration of therapeutic docetaxel.

Study description

Background summary

Docetaxel is an important chemotherapeutic agent in the treatment of several cancer types. However, tumour resistance to docetaxel remains a major challenge. Since positron emission tomography (PET) and radiolabelled anticancer agents provide a unique means for personalized treatment planning, the new PET tracer [11C]docetaxel was developed by labelling the drug docetaxel with the short-lived positron-emitting radionuclide carbon-11. [11C]docetaxel uptake may be predictive of tumour response and thereby offer a means of avoiding ineffective, but toxic treatment in individual patients. For other radiolabelled anticancer agents, however, it has been demonstrated that the therapeutic dose can affect the tumour uptake of the tracer dose. Therefore, the effect of the therapeutic dose of the drug docetaxel on [11C]docetaxel uptake by tumours should be investigated.

Study objective

1) To study whether [11C]docetaxel uptake by tumours predicts tumour uptake of therapeutic docetaxel.
2) To study the effects of therapeutic docetaxel on venous metabolite fractions

of [11C]docetaxel.
3) To study the relation between tumour blood flow and [11C]docetaxel uptake in tumours after administration of therapeutic docetaxel.

Study design

An observational study with invasive measurements. The procedure consists of a low dose CT scan, intravenous administration of [15O]H2O and [11C]docetaxel, PET acquisition for about 70 min and venous blood sampling during PET scanning. This procedure will be repeated on the same day. During the second PET scan the therapeutic dose of docetaxel will be administered.

Study burden and risks

Risks associated with participation in this study are related to 1) radiation exposure; 2) idiosyncratic reaction to the tracer [11C]docetaxel; 3) intravenous cannulation; 4) blood sampling; 5) discomfort during scanning; 6) administration therapeutic docetaxel.

1) Radiation exposure
The total amount of radiation burden is 6 mSv.

2) Idiosyncratic reaction to the tracer [11C]docetaxel
No [11C]docetaxel-induced side-effects are expected.

3) Intravenous cannulation
There is a very small risk of infection, bleeding or hematoma.

4) Blood sampling
The total amount of blood taken for investigation is 160 ml.

5) Discomfort during scanning
It may be uncomfortable to lie motionless in the PET camera and it may cause some subjects to feel anxious.

6) Administration of therapeutic docetaxel
Docetaxel treatment can cause several side-effects. For a complete overview of docetaxel-induced side-effect we refer of the SPC of docetaxel.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age: 18 years of age or older
- Patients with an advanced solid tumour planned to receive docetaxel treatment
- Disease with a malignant lesion >= 1.5 cm diameter within the chest as measured by Response Evaluation Criteria in Solid Tumors (RECIST)
- Life expectancy of at least 12 weeks
- ECOG performance status of 0 - 2
- Neutrophils > 1.5 x 109/L
- Haemoglobin > 6.0 mmol/l
- Able to comply with study procedures
- Written Informed Consent

Exclusion criteria

- Previous treatment with taxanes
- Claustrophobia
- Pregnant or lactating patients
- Patients having metal implants (e.g. pacemakers)

- Concurrent treatment with experimental drugs

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2010
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	[11C]docetaxel and [15O]H2O

Ethics review

Approved WMO Date:	01-12-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-01-2010
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
EudraCT	EUCTR2009-013424-23-NL
CCMO	NL28587.029.09