Microdosing as a tool to individualize docetaxel dosing: development of a limited sampling model

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON49402

Source
ToetsingOnline

Brief title
The MicroDoce study

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Breast-, prostate and non-small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: Subsidies

Intervention

Keyword: Docetaxel, Microdose, Pharmacokinetics

Outcome measures

Primary outcome

Pharmacokinetics of a microdoce- and a therapeutic dose docetaxel

Secondary outcome

Does not apply

Study description

Background summary

Docetaxel is a widely used chemotherapeutic agent accros a variety of tumor types, including breast-, lung- and non-small cell lungcancer. Although its dosing is individualized on body surface area (BSE), variability in docetaxel exposure explains docetaxel variability in toxicity. Docetaxel is mainly metabolized by the cytochrome P450 isoenzyme (CYP3A). In cancer patients CYP3A activity may vary a 4-fold. Previous studies showed that a microdose of midazolam -- like docetaxel a substrate for CYP3A - can reliably predict the pharmacokinetics of midazolam in therapeutic dose. Therefore, clearance of a microdose docetaxel might be a good predictor for clearance, and thus exposure of therpeutic dose docetaxel. The relationship may guide future docetaxel dosing individualization studies based on CYP3A phenotyping to optimize treatment and reduce unwanted toxicity.

Study objective

The primary objective of this study is to establish the relationship between microdose and therapeutic dose docetaxel pharmacokinetics. Our secondary objective is to develop a limited sampling model of microdose docetaxel pharmacokinetics to predict therapeutic dose docetaxel pharmacokinetics.

Study design

Observational, prospective cohort study

Intervention

All patiënts will be administered a single intraveneous microdose(1000 microgram) docetaxel, before regular treatment with the therapeutic dosce. After the microdose and therapeutic dose blood samples will be collected for determination of their pharmacokinetics.

Study burden and risks

The nature and extent of the burden associated with participation are considered to be minimal, since the only exrta interventions outside of routine clinical care are administration of midazolam and collection of blood samples. There is no individual benefit to be expected from participation.

Contacts

Public
Meander Medisch Centrum

Maatweg 3
Amersfoort 3813TZ
NL
Scientific
Meander Medisch Centrum

Maatweg 3
Amersfoort 3813TZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with breast-, prostate and non-small cell lung cancer (NSCLC), who are planned for routine treatment with docetaxel

Exclusion criteria

Absence of informed consent

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Taxotere
Generic name:	Docetaxel
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	13-10-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-03-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-08-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-10-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-03-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28213

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2016-003785-77-NL
CCMO	NL59339.100.16
OMON	NL-OMON28213