Lean Body Mass as a determinant of docetaxel pharmacokinetics and toxicity (LEANDOC)

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Primary objective:To determine which anthropometric parameters, LBM, total body weight (TBW) or BSA correlates best to docetaxel exposure (AUC). Secondary objectives:To determine if occurrence of docetaxel toxicity can be related to dose/LBM.To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON39781

Source
ToetsingOnline

Brief title
LEANDOC

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Prostatic disorders (excl infections and inflammations)

Synonym
Breast cancer, Mamma carcinoma, Prostate cancer, Prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Eigen buget ziekenhuizen

Intervention

Keyword: Docetaxel, Lean Body Mass, Pharmacokinetics

Outcome measures

Primary outcome

For evaluating the primary objective linear regression analysis is performed between the measures of docetaxel exposure (AUC0-*) and LBM respectively BSA. Coefficients of determination (R2) of both lines will be statistically evaluated.

Secondary outcome

For comparing multiple determinants (LBM, BSA, TBW) an linear regressiion analysis will be performed.

Adverse effect and toxicity events are scored via the CTCAE criteria. All events are scored between Grade 1 and 4 equally dose delays, dose reductions and treatment termination. Overall toxicity will be defined as DLT comprising (any grade 3/4 toxicity, dose delay, reduction or termination) and will be correlated to the dose docetaxel/ anthropometric parameters (LBM, BSA and TBW).

Study description

Background summary

Docetaxel is used as a first line anti-cancer drug in the treatment of several cancers, mainly breast- and metastatic castration-resistant prostate carcinoma.

Most anti-cancer drugs are being dosed based on patients estimated Body Surface Area in order to equalize total drug exposure. Nevertheless, docetaxel treatment is character-ized by highly interindividual pharmacokinetic variation

leading to toxicity and under-treatment.

For some anti cander drugs, including docetaxel, other anthropometric parameters, such as Lean Body Mass (LBM), have been suggested to be better than Body Surface Are (BSA) as a determinant for dosing.

Study objective

Primary objective:
To determine which anthropometric parameters, LBM, total body weight (TBW) or BSA correlates best to docetaxel exposure (AUC).

Secondary objectives:
To determine if occurrence of docetaxel toxicity can be related to dose/LBM.
To determine which methods to measure LBM: DEXA, Bioelectrical Impedance As-sessments (BIA) or formula estimates are accurate enough for dosing calculations. to be used for dosing docetaxel.

Study design

Observational, Multicentre, Pilot Study

Study burden and risks

1. The needle used for bloodsampling can cause discomfort or pain near the puncture site.
2. The risk of the amount of used X-rays at the DEXA scan is negligible. It is important to be aware of (possible) pregnancy due to possible teratogenicity of exposure of the unborn child to X-rays.
3. The risk of a treatement with docetaxel will not change. Subjects can experience side effects of docetaxel.

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

1. Subject is at least 18;
2. Subject is able and willing to sign the Informed Consent Form prior to screen-ing evaluations;
3. Female subject diagnosed with breast carcinoma and will receive docetaxel treatment according to standard hospital protocol (TAC regimen) or male subject diagnosed with metastatic castration-resistant prostate carcinoma and will receive docetaxel treatment according to standard hospital protocol (PRODOC regimen)
4. Subject has an live expectancy of 12 weeks or greater;
5. Absolute neutrophile count (ANC) > 1.5 x 109/L;
6. Platelet count > 100 x 109/L;
7. Serum creatinine <= 2 x ULN;
8. Total bilirubin level < 1.5 x ULN;

Exclusion criteria

1. Moderate or severe liver impairment; [ALAT and/or ASAT >= 1.5 ULN] and [AF >= 2.5 ULN] ;
2. Current therapy with any drug, dietary supplements, or other compounds, or have been used in the last 2 weeks prior to the docetaxel administration, known to inhibit or induce CYP3A4 as mentioned on the list in appendix A.;
3. Inability to understand the nature and extent of the study and the procedures required;

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-09-2012
Enrollment:	40
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:	08-02-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-05-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-06-2013

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-02-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2011-005168-14-NL
CCMO	NL38529.091.12