The relationship between the conversion and excretion of docetaxel and paclitaxel and variation in DNA.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25570

Source
NTR

Brief title
N/A

Health condition

cancer, docetaxel, paclitaxel, pharmacokinetics, pharmacodynamics, pharmacogenetics

Sponsors and support

Primary sponsor: sponsor: Erasmus Medical Center, Daniel den Hoed Cancer Center
address: P.O. Box 5201
postal code: 3008 AE
city: Rotterdam
country: The Netherlands
phone: +31 (0)10 4391568
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email: hdc@erasmusmc.nl
Source(s) of monetary or material Support: KWF Kankerbestrijding
Postbus 75508
1070 AM Amsterdam

Intervention

Outcome measures

Primary outcome

Pharmacokinetic outcomes: AUC and Clearance;

Measured by: NONMEM population analysis.

Secondary outcome

Pharmacodynamic outcomes: Toxicity (grade of neutropenia, leucopenia, thrombocytopenia, anemia, neutropenic fever, neurotoxicity);

Measured by: Clinicians assessment during treatment, grading according to CTC criteria.

Study description

Background summary

The purpose of this study is to establish pharmacogenetic markers for therapy with the taxanes paclitaxel and docetaxel. At present, toxicity is still a major clinical problem, and interindividual variability in pharmacokinetics and pharmacodynamics is extensive and largely unexplained. Toxicity and outcome are often related to pharmacokinetics. At present, there is no individualisation of taxane treatment other than dose adjustment for body suface area. Genetic variability is one of the most promising biomarkers that may be used to predict taxane pharmacokinetics and pharmacodynamics. This could minimize side-effects and maximize therapeutic efficacy in taxane treated patients.

Study objective

The inter-individual pharmacokinetic and pharmacodynamic variability for the anticancer drugs docetaxel and paclitaxel is due to patient characteristics, genetic variability and life style factors.

Study design

1. DNA sampling;

2. At 4 different timepoints blood sampling for PK analysis.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Age >18 years;

2. Treated with docetaxel or paclitaxel;

3. Written informed consent;

4. Written informed consent regarding single bloodsample for DNA analysis.

Exclusion criteria

Use of known CYP3A4 inducers/inhibitors.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-05-2004
Enrollment:	700
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-04-2010
Application type:	First submission

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
NTR-new	NL2187

Register	ID
NTR-old	NTR2311
Other	Medical Ethical Approval Board Erasmus Medical Center : 03-264
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A