Observational study to evaluate pharmacokinetics and pharmacodynamics of docetaxel, paclitaxel, doxorubicin, gemcitabine, vinorelbine, and capecitabine in elderly patients.

Published: 03-05-2012
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Primary objective To determine the relation between age and pharmacokinetics of docetaxel, paclitaxel, doxorubicin, gemcitabine, vinorelbine and capecitabine, respectively. Secondary objectives All here cited secondary endpoints will be separately...

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

Summary

ID

NL-OMON47924

Source
ToetsingOnline

Brief title
SENIOR (Study to Evaluate Neoplasmatic drugs In Older Recipients)

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer malignancies

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: elderly, modelling, pharmacokinetics

Outcome measures

Primary outcome

Pharmacokinetic parameters Serum concentrations of each included agent (absolute values and relative to data retrieved from adult patients < 70 years)

Secondary outcome

Pharmacodynamic parameters (serious) adverse events effectiveness (PFS, RR)

Study description

Background summary

The majority of all cancers is diagnosed in elderly patients (61% in >= 65 years) and this number is increasing. Elderly patients are routinely treated with chemotherapeutic agents. However, this potentially toxic therapy may have a higher risk profile in the elderly. Appropriate dosing guidelines do not exist due to a paucity of relevant PK-PD data in elderly. Therefore, the aim of this study is to characterize the pharmacokinetics of doxorubicin and gemcitabine in patients aged \u2265 70 years. Our premise is that the PK profiles of these drugs alter with increasing age. Two factors are postulated to correlate with pharmacokinetics of each chemotherapeutic agent: (1) age: it is not clearwhat the influence of age is on the PK profiles of the included chemotherapeutics; (2) organ function: the influence of several organ functions, amongst others including renal and hepatic functions, on pharmacokinetics in adult patients < 70 years is well established for the chemotherapeutics included in this study. The predictive value of these functions as a sole factor in elderly patients, remains unclear thus far. The influence of other parameters, e.g. frailty assessments, as confounding factors in determining pharmacokinetics by age in elderly patients will be explored if routinely assessed and documented.

Study objective

Primary objective To determine the relation between age and pharmacokinetics of docetaxel, paclitaxel, doxorubicin, gemcitabine, vinorelbine and capecitabine, respectively. Secondary objectives All here cited secondary endpoints will be separately analysed for doxorubicin and gemcitabine: \u2022 To correlate the pharmacokinetics of elderly patients with organ functions, including various laboratory renal and hepatic functions; \u2022 To correlate pharmacokinetics of elderly patients with clinical and laboratory toxicity; \u2022 To determine the correlation between pharmacokinetics of elderly patients and hematologic toxicity; \u2022 To correlate pharmacokinetics of elderly patients with progression free survival (PFS); \u2022 To correlate pharmacokinetics of elderly patients with response rate (RR).

Study design

Patients aged 70 years or older will be included in the study if they will receive intravenously administered docetaxel, paclitaxel, doxorubicin, gemcitabine, vinorelbine or capecitabine. The treatment regimen is left to the discretion of the treating oncologist in accordance with current standard of care. Routine measurements of organ functions, (other) laboratory parameters, and disease and performance status will be conducted by the treating oncologist, clinical chemistry or pathology department, complying with current standard of care. Frailty assessments will also be taken into account if routinely assessed and documented. Additional blood samples for pharmacokinetic analysis will be withdrawn and analysed by the GLP-licensed Department of Pharmacy & Pharmacology of the Antoni van Leeuwenhoek using validated bio-analytical methods.

Study burden and risks

All patients will visit the hospital, receive chemotherapeutics, and undergo blood sample collections according to current standards as part of routine medical care. Additional blood samples will be collected for pharmacokinetic analysis.

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. Planned to receive docetaxel, paclitaxel, doxorubicin, gemcitabine, vinorelbine, or capecitabine as regular treatment for cancer; 2. Age >= 70 years; 3. Able and willing to give written informed consent prior to participation in the trial; 4. Able and willing to undergo blood sampling for pharmacokinetics.

Exclusion criteria

No exclusion criteria are applicable.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	02-08-2012
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	03-05-2012
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-05-2012
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	30-05-2012
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-05-2012
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	09-02-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-02-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	29-03-2016
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	29-03-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	28-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-03-2019
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL39647.048.12

Study results

Date completed:	07-09-2023
Results posted:	07-09-2023

Actual enrolment: 337

First publication
23-09-2018