Predictors for Chemotherapy Tolerance and Toxicity in Elderly Cancer Patients

Published: 25-10-2012
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The objective of this study is to Identify relevant geriatric instruments and compose a clinical model to predict tolerance and toxicity in elderly cancer patients who are treated with chemotherapy for their (metastasized) malignancy.

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

Summary

ID

NL-OMON39958

Source
ToetsingOnline

Brief title
P-TOP

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
chemotherapy tolerance, toxicity

Research involving
Human

Sponsors and support

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

Intervention

Keyword: chemotherapy, geriatric medicine, oncology, tolerance

Outcome measures

Primary outcome

Primary outcome is chemotherapy tolerance, defined as the ability to complete the first three cycles. This will then be correlated to the scores from the questionnaires.

Secondary outcome

Secondary outcome is (CTCAE graded) toxicity. This will then be correlated to the scores from the questionnaires.

Study description

Background summary

Due to the aging of many western populations the number of people above 65 years of age is rapidly increasing. Furthermore high age is associated with increased cancer risk. With increasing age, physiological reserves decrease and people become more vulnerable to disease and stress, resulting in more co-morbidities. This makes elderly patients a very heterogeneous group. Because of this advanced age is one of the major exclusion criteria of many large clinical trials. However, as a resultcurrent knowledge about chemotherapy tolerance and toxicity in elderly is limited and oncology lacks proper clinical instruments to accurately and objectively differentiate between fit and frail elderly patients

Study objective

The objective of this study is to Identify relevant geriatric instruments and compose a clinical model to predict tolerance and toxicity in elderly cancer patients who are treated with chemotherapy for their (metastasized) malignancy.

Study design

Multi-center prospective cohort study. For development of the predictive model

we will use five validated questionnaires about health and functioning and a short validated mobility test from geriatric medicine. Assessment will be preceding chemotherapeutic treatment. Furthermore information from the medical record will be used. No extra invasive measurements will be made for this study.

Study burden and risks

Expectation is participation to this study will have negligible risks and no advantages or disadvantages for the participants. Participating requires a one time investment of 30-60 minutes. Treatment does not depend on this study. There are no invasive measurements.

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

- Patients with a metastasized malignancy that will be treated with palliative chemotherapy.
- Patients with a non hogdkin lymphoma or a multiple myeloma that will be treated with chemotherapy
- Patients that are at least 70 years old at start of chemotherapy.
- Informed consent.

Exclusion criteria

- Patients who have unadequate command of the Dutch language.
- Patients who are cognitive impaired.
- Patients with CNS metastases.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-11-2012
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	25-10-2012
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-06-2013
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

No registrations found.

In other registers

Register	ID
CCMO	NL42055.100.12