Optimization of systemic treatment strategies in elderly patients with advanced solid malignancies: OptiMal trial

Published: 02-07-2013
Last updated: 15-05-2024

To assess whether the presence of a myelodysplastic syndrome, idiopathic cytopenia of undetermined significance (ICUS) or idiopathic dysplasia of undetermined significance (IDUS), correlates with treatment intensity and clinical outcome in older...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON47698

Source
ToetsingOnline

Brief title
OptiMal

Condition

- Metastases

Synonym
advanced cancer, palliative chemotherapy

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: divisie I beheer B.V.

Intervention

Keyword: cancer, elderly, toxicity

Outcome measures

Primary outcome

* Toxicity of treatment due to any cause

* Prevalence of MDS/IDUS in the studied group of patients

Secondary outcome

• Prevalence of sarcopenia in the studied group of patients

• (Termination, postponement or dose modification) of treatment due to

any cause

• Overall survival

• Response to treatment

• Progression free survival

• Difference in combination therapy versus monotherapy

• Quality of life

Study description

Background summary

The incidence of cancer increases with age. More than fifty percent of all newly diagnosed patients in the Western world is older than 60 years of age. Treatment with a combination of cytotoxic agents is often indicated as (palliative) treatment in patients with advanced malignancies. It is unclear to what extent older patients should receive similar treatment as younger patients, because in most randomized clinical trials in which standard treatment strategies have been established, the mean age of patients was below 60 years. Apart from the fact that elderly patients are often less resilient,

sometimes even frail and have more co-morbidity, including impaired cognitive function, also other factors may play a role in potential serious toxicities compared to younger patients.
Myelotoxicity is an important factor in the completion of treatment in these patients and may often lead to dose reduction, postponement of therapy and hospitalization. There is consistent evidence that patients with sarcopenia present with more severe toxicity during treatment with cytotoxic agents. This muscle depletion is age related and may be an indication for dose adjustment especially in the elderly. We assume that the myelodysplastic syndrome may contribute to myelotoxicity in this group of patients as well. It*s occurrence increases with age and its incidence and prevalence have increased significantly over the past 20 years. It is often underdiagnosed and unrecognized.
Considering the increasing age of the entire population, it is of utmost importance to develop accurate methods to individualize treatment strategies in elderly patients. We hypothesize that a Comprehensive Geriatric Assessment with measurement of human body composition with computerized tomography and / or a standardized flow cytometry test to determine bone marrow capacity will provide an accurate tool to optimize treatment strategies in elderly patients with advanced malignancies.

Study objective

To assess whether the presence of a myelodysplastic syndrome, idiopathic cytopenia of undetermined significance (ICUS) or idiopathic dysplasia of undetermined significance (IDUS), correlates with treatment intensity and clinical outcome in older patients with advanced malignancies receiving palliative chemotherapy.
We will study the relation between sarcopenia, comprehensive geriatric assessment en pharmacokinetics with treatment related toxicity as well.

Study design

A prospective clinical trial is designed. Patients will be treated according to current standard of care. Included patients will undergo a geriatric assessment prior to treatment. This assessment consists of several questionnaires and functional tests, assessment of body composition (CT scan) and a peripheral blood and (optional) bone marrow examination including a flow cytometric assessment of hematopoietic cells. The latter will be used to determine whether myelodysplasia or ICUS or IDUS can be diagnosed. We will monitor patients* charts during treatment and post treatment for a maximum of 6 months. We will register toxicity, termination, postponement or dose modifications of treatment due to any cause.
During follow up we will ask patients to fill out the EORTC QLQ C-30 questionnaire.

Study burden and risks

Patients will be submitted to a geriatric assessment. The assessments consits of various questionnaires and functional tests and will have a total duration of about 30 minutes. After that a venapunction will be taken, potentially followed by the bone marrow aspirate, which will also take 15 minutes. After the aspirate patient wll have to lay down for 10 minutes to apply pressure to the punctionwound.

In a review by the British Society of Haematology on adverse events (AE) associated with a diagnostic bonemarrow aspirate / biopsy in 0.08% of procedures an AE was seen. In most cases there was bleeding (0.06%) en in fewer cases pain (0.01%). In 0.015% of cases a serious AE occured. In a study on pain in bone marrow aspiration and biopsies in 120 patients, patients reported a low painscore and most patients (97%) were satisfied with local anaesthesia during the procedure.

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

Age >= 70 years; Diagnosis of advanced cancer of colorectum, breast, prostate, stomach or esophagus; Standard palliative treatment with cytotoxic agents will be started; Life expectancy >= 3 months; Able to give informed consent

Exclusion criteria

Presence of cytopenia due to iron-,vitamin B12 and folic acid deficiency or hemolysis, unless adequately supplemented. GFR <30 ml/min; serum AST and ALT >= 2,5 ULN, in case of liver metastases serum AST and ALT >= 5 x ULN

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-09-2013
Enrollment:	85
Type:	Actual

Ethics review

Approved WMO

Date:	02-07-2013

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 27004
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL42444.029.13
OMON	NL-OMON27004