Treatment strategy in elderly patients with cancer

Gepubliceerd: 24-09-2013 Laatst bijgewerkt: 15-05-2024

Our hypothesis is that assessment of bone marrow capacity reserve can predict treatment related toxicity.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27004

Bron
NTR

Verkorte titel
OptiMal

Aandoening

Diagnosis of advanced cancer of colorectum, breast or prostate

Gemetastaseerd Colorectaal-, borst- of prostaatkanker

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

-Toxicity of treatment due to any cause
- Prevalence of MDS/IDUS in the studied group of patients

Toelichting onderzoek

Achtergrond van het onderzoek

The purpose of this study is 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. 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

Doel van het onderzoek

Our hypothesis is that assessment of bone marrow capacity reserve can predict treatment related toxicity.

Onderzoeksopzet

from date of study inclusion until 30 days after end of treatment

Onderzoeksproduct en/of interventie

All patients will be submitted to blood tests, a bone marrow (BM) examination, and comprehensive geriatric assessment prior to start of treatment. A readily available CT scan will be used to measure
lumbar skeletal muscle. In case of absence of a recent CT scan, a CT scan of the abdomen will be performed. In addition, limited pharmacokinetics (PK) will be performed.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age older 70 years

- Diagnosis of advanced cancer of colorectum, breast or prostate

- Standard first line palliative treatment with cytotoxic agents will be started (Folfox, Xelox, capecitabine, paclitaxel or docetaxel)

- Estimated life expectancy ¡Ý 3 months

- Able to give informed consent

- WHO performance status ¡Ü 2

- Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the treatment and follow-up schedule; those conditions should be assessed with the patient before registration in the trial
- No other severe medical or psychiatric conditions that in the judgment of the investigator renders the patient inappropriate for inclusion in this study.
- Before patient registration, written informed consent must be given and documented to

ICH/EUCGCP, national/local regulatory requirements and the local rules followed in our institution

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Presence of cytopenia due to iron-, vitamin B12 and folic acid deficiency or hemolysis, unless adequately supplemented.

- Creatinine clearance ¡Ü 30 ml/min

- Serum AST and ALT ¡Ý 2.5 x ULN, in case of liver metastases serum AST and ALT ¡Ý 5 x ULN

- In case of therapy with Docetaxel/Paclitaxel serum bilirubin ¡Ý 1.5 x ULN

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2013
Aantal proefpersonen:	85
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-09-2013

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47698
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3972
NTR-old	NTR4186
CCMO	NL42444.029.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON47698

Resultaten

Samenvatting resultaten
N/A