Docetaxel met carboplatine versus docetaxel, een gerandomiseerde fase 2 studie bij patiënten met hormoonongevoelig prostaatkanker na eerdere respons op docetaxel-bevattende chemotherapie: RECARDO STUDIE.

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The progressionfree survival during treatment with carboplatin plus docetaxel is significantly better compared to standard treatment with docetaxel monotherapy.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27233

Bron
Nationaal Trial Register

Verkorte titel
RECARDO

Aandoening

Hormone refractory prostate cancer

Ondersteuning

Primaire sponsor: VU Medisch Centrum
Overige ondersteuning: VU Medisch Centrum

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Progression-free survival

Toelichting onderzoek

Achtergrond van het onderzoek

Docetaxel has been accepted as the new standard for treatment of patients with metastatic hormone-refractory prostate cancer (HRPC). Moreover, docetaxel-based chemotherapy is the reference treatment for development of new treatment options in HRPC. Few treatment options are available for patients who progressed on first line docetaxel-based chemotherapy (CT). While single-agent carboplatin has modest activity in HRPC, carboplatin chemotherapy could induce a synergistic effect when combined with taxanes in patients resistant to taxane-based chemotherapy. The combination of docetaxel (60 mg/m²) plus carboplatin (AUC4) has demonstrated clinical activity in patients who definitively progressed after docetaxel-based therapy. In this study the efficacy of docetaxel/carboplatin combination therapy relative to docetaxel monotherapy will be evaluated in docetaxel-sensitive patients who progressed on first line docetaxel-based CT.

Doel van het onderzoek

The progressionfree survival during treatment with carboplatin plus docetaxel is significantly better compared to standard treatment with docetaxel monotherapy.

Onderzoeksopzet

Every 9 weeks. Measurements through PSA, chest X-ray or CT scan, abdominal/pelvic CT scan and bone scan.

Onderzoeksproduct en/of interventie

Arm A: Docetaxel 75 mg/m² q3 weeks + prednisone 5 mg bid;

Arm B: Docetaxel 60 mg/m² q3 weeks + prednisone 5 mg bid + carboplatin AUC (4) q3 weeks.

Treatment in both arms will be continued until progression, unacceptable toxicity or 10 courses (whichever comes first).

Contactpersonen

Publiek

VUmc, Dept. of Medical Oncology
De Boelelaan 1117
Winald Gerritsen
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4444356

Wetenschappelijk

VUmc, Dept. of Medical Oncology
De Boelelaan 1117
Winald Gerritsen
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4444356

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Histologically proven prostate adenocarcinoma;

2. Hormone refractory prostate cancer;

3. Patients must have had PSA and/or clinical response and progression free for >3 months on first line chemotherapy with docetaxel for HRPC;

4. Patients must have progressed on prior chemotherapy with docetaxel; progression at study entry is defined as (confirmed) PSA progression and/or objective tumor progression whichever comes first (see 6.2.3);

5. Last PSA value ≥ 5 ng/ml within 2 weeks prior to registration (HYBRITECH equivalent);

6. Patients without surgical castration must continue on LHRH agonist therapy;

7. Age ≥ 18 years;

8. ECOG performance status ≤2;

9. Gleason score ≥ 7;

10. Adequate haematological functions as assessed by neutrophils >1,5x109/, platelets >100x109/L;

11. Adequate liver function as assessed by bilirubin <1,5 times the upper limit of the normal range and transaminases <5 times the upper limit of normal range in case of liver metastases and <2,5 times the upper limit of the normal range in absence of liver metastases;

12. Adequate renal function as assessed by serum creatinine <150 µmol/l (<1,7 mg/dl);

13. Psychological, familial and geographical conditions must permit adequate medical follow up and compliance with the study protocol;

14. Written informed consent according to ICH-GCP.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. More than 1 line of chemotherapy;

2. No prior platinum allowed;

3. Radiotherapy within 2 weeks prior to treatment start;

4. Concurrent treatment with other experimental drugs;

5. Evidence of symptomatic brain and leptomeningeal metastatic disease;

6. Previous or concurrent malignancies at other sites (except basal squamous cell carcinoma of the skin);

7. Uncontrolled systemic disease or infection;

8. Severe concomitant disease for which chemotherapy is contra-indicated.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2010
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-09-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35127
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2923

Register	ID
NTR-old	NTR3070
CCMO	NL27431.029.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35127

Resultaten

Samenvatting resultaten
N/A