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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27233

Source
Nationaal Trial Register

Brief title
RECARDO

Health condition

Hormone refractory prostate cancer

Sponsors and support

Primary sponsor: VU Medisch Centrum
Source(s) of monetary or material Support: VU Medisch Centrum

Intervention

Outcome measures

Primary outcome

Progression-free survival

Secondary outcome

1. Safety and tolerability;

2. Magnitude and duration of PSA response;

3. Tumor response in measurable direase;

4. Overall survival;

5. Quality of life.

Study description

Background summary

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/m^2) 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.

Study objective

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

Study design

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

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2010
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-09-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35127
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2923
NTR-old	NTR3070
CCMO	NL27431.029.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35127

Study results

Summary results
N/A