A randomized phase II trial of docetaxel plus carboplatin versus docetaxel in hormone refractory prostate cancer patients who have progressed after response to prior docetaxel chemotherapy: RECARDO STUDY

Published: 20-03-2009
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Primary objectives:* Progression-free survival (PFS) defined as either of the following occurrences, whichever comes first:o PSA progression o Progressive disease according to RECIST when measurable diseaseSecondary objectives:* Toxicity profile.*...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON35127

Source
ToetsingOnline

Brief title
RECARDO

Condition

- Reproductive neoplasms female malignant and unspecified
- Prostatic disorders (excl infections and inflammations)

Synonym
hormone refractory prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: verrichter

Intervention

Keyword: carboplatin, docetaxel, metastatic, prostate cancer

Outcome measures

Primary outcome

Progression free survival.

Secondary outcome

Tolerability, safety, PSA and tumor response, survival, QoL.

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 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

Primary objectives:
* Progression-free survival (PFS) defined as either of the following

occurrences, whichever comes first:
o PSA progression
o Progressive disease according to RECIST when measurable disease
Secondary objectives:
* Toxicity profile.
* PSA response and duration of PSA response.
* Objective tumor response when measurable disease.
* Survival.
* QoL.

Study design

Multicenter randomized, open-label, national phase II study with parallel design. Randomization (1:1) to:
1. Arm A: docetaxel 75 mg/m² q3 weeks + prednisone 5 mg bid
2. Arm B: docetaxel 60 mg/m² q3 weeks + prednisone 5 mg bid + carboplatin AUC (4) q3 weeks
Treatment in both arms will be until progression or unacceptable toxicity (maximum 10 courses).
Pilot fase: Forty patients will be randomized (20 patients per arm). PSA response (* 50%) must occur in at least 6 patients in this pilot. Toxicity in both arms must be comparable and grade 3/4 non-haematological toxicity may not be >10% and/or febrile neutropenia must not occur in more than 3 patients in both arms.
Formal interim analysis after 75 patiens.
Follow-up 15 months.
150 patients. Planned inclusion: approx. 70 patients per year.

Intervention

Treatment with combine carboplatin and docetaxel or docetaxel alone.

Study burden and risks

Risk: Adverse effects of combined carboplatin and docetaxel or of docetaxel alone.
Burden: The study is in line with current regular treatment in terms of visits and procedures: hematology, biochemistry and PSA q3 weeks, imaging q9 weeks. For study purposes only the QoL questionnaire (Functional Assessment of Cancer Therapy*Prostate, FACT-P) is filled in q3 weeks.

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

1. 18 years and above.
2. Histologically proven hormone refractory prostate adenocarcinoma.
3. PSA and/or clinical response on prior docetaxel-based chemotherapy with a progression free interval of over 3 months.
4. Last PSA value * 5 ng/ml within 2 weeks prior to registration (HYBRITECH equivalent)
5. Patients without surgical castration must continue on LHRH agonist therapy
6. ECOG performance status * 2
7. Gleason score 8-10
8. Adequate haematological, liver and renal function.

Exclusion criteria

1. More than 1 line of chemotherapy.
2. Prior platinum chemotherapy.
3. Radiotherapy within 2 weeks prior to treatment start.

4. Uncontrolled hypercalcemia.
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).

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2009
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Carboplatin
Generic name:	carboplatine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Taxotere
Generic name:	docetaxel
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-03-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-05-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-07-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-02-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-05-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-05-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-05-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-05-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-06-2010

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-06-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-08-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-09-2010
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: 27233
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	clinicaltrials.gov, registratienummer nog niet bekend
EudraCT	EUCTR2007-004335-39-NL
CCMO	NL27431.029.09
OMON	NL-OMON27233