A Randomized, Open Label, Phase III, Multicenter, 2-Arm Study of Androgen deprivation +/- Taxoterere* (Docetaxel) for Non metastatic Prostate Cancer Patients with a Rising PSA.

Published: 07-08-2009
Last updated: 09-11-2024

To evaluate and compare progression free survival (PSA) between the two treatment arms.

Ethical review	Approved WMO
Status	Completed
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON35597

Source
ToetsingOnline

Brief title
PSA-ERECT

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- Prostatic disorders (excl infections and inflammations)

Synonym
Prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Scandinavian Prostate Cancer Group
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Androgen deprivation, Non-metastatic prostate cancer, Rising PSA, Taxotere

Outcome measures

Primary outcome

To evaluate and compare progression free survival (PFS) between the two

treatment arms.

Secondary outcome

To evaluate and compare

· Metastasis free survival

· Cancer specific survival

· Overall survival

· Quality of Life (QoL)

· PSA doubling time after progression

Study description

Background summary

Chemotherapy has historically been regarded as not effective for the treatment of androgen independent prostate cancer. Only Taxotere (docetaxel) and prednisone have recently been shown to confer a survival advantage to patients with advanced disease, raising the possibility that chemotherapy may contribute to the cure of patients when applied earlier in the natural history.

Study objective

To evaluate and compare progression free survival (PSA) between the two

treatment arms.

Study design

The trial is a prospective, open, multinational, multicentre, randomised phase III trial.

Intervention

Arm A: Antiandrogen alone (bicalutamide 150 mg x 1)
Arm B: Antiandrogen (bicalutamide 150 mg x 1) + docetaxel (Taxotere®) 75mg/m2 (max. 2.0 m2) i.v. in 60 minutes on day 1. One cycle is 21 days. Docetaxel will be given for up to 8-10 cycles or until unacceptable toxicity or consent withdrawal whichever comes first.

Profylactic mammary gland irradiation should be given to all patients before treatment starts.

Study burden and risks

The main side effects of docetaxel are neutropenia, anaphylactoid type reactions, skin toxicity and nail disorders, digestive toxicity (oral mucositis, nausea, vomiting and diarrhoea), peripheral neurotoxicity, alopecia, asthenia/fatigue and peripheral oedema.

Patients receiving taxotere may have a longer progression free survival.

Contacts

Public
Scandinavian Prostate Cancer Group

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131 42 Nacka
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Men > 18 and <=80 years of age.
- WHO/ECOG performance status 0 - 1.
- Histological proven adenocarcinoma of the prostate.
- Patients who are planned to receive antiandrogen (bicalutamide 150 mg x 1) treatment,
· After Curative treatment
o Prostatectomy: PSA > 10 OR PSA DT < 12 months and PSA > 0.5 (PSA doubling time calculation must start at a minimum value of > 0.5)
o Radiation: PSA > +2.0 above nadir and PSA >10 OR PSA DT < 12 months and PSA > 0.5. (PSA bouncing after radiotherapy should be excluded according to the local traditions, and PSA doubling time calculation must start at a minimum value of > 0.5)
· In locally advanced (or local not suitable for curative therapy) prostate cancer patients, PSA < 100 is required before inclusion AND one of the following
o PSA DT < 12 months or
o PSA >20 or
o Gleason score 8-10,
- Previous hormonal therapy in conjunction with radiotherapy is allowed, provided that the total duration of therapy does not exceed 12 months and has to be stopped > 12 months ago.
- Testosterone value > 5 nmol/l
- Adequate haematological-, liver- and kidney function.
- Negative bone scan performed no more than 3 months prior to randomisation.
- Additional CT or ultrasound of thorax, abdomen and/or pelvis is optional
- Written informed consent.

Exclusion criteria

- Positive Bone scan.
- Any distant metastasis detected by CT or ultrasound.
- Patients with a history of previous malignant disease. Exceptions should be made for basal cell carcinoma (BCC) and squamous cell carcinoma of the skin. Exceptions should also be made for curatively treated malignant disease, which has been disease free for the past 5 years.
- Previous chemotherapy or randomised in SPCG 12/AdPro or SPCG 13/AdRad.
- Systemic corticosteroids within 6 months prior to randomisation.
- Unstable cardiovascular disease, including myocardial infarction, within 6 months prior to randomisation.
- Active untreated infectious disease, including tuberculosis, MRSA.
- Active gastric ulcer.
- Known hypersensitivity to Polysorbate 80 (an excipient of docetaxel)
- Other serious illness or medical condition.
- Symptomatic peripheral neuropathy >= CTCAE grade 2.
- Patients who by altered physical or psychological state not are able to co-operate or participate in the trial.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-03-2010
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Taxotere
Generic name:	Docetaxel
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	07-08-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-01-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-01-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-04-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-04-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-04-2010
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-05-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-06-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-06-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2008-003138-33-NL
CCMO	NL28063.078.09