A Randomized Phase 3 Study Comparing Standard First-Line Docetaxel/Prednisone to Docetaxel/Prednisone in Combination with Custirsen (OGX-011) in Men with Metastatic Castrate Resistant Prostate Cancer

Published: 14-04-2011
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To ascertain whether the survival time distribution for patients randomized to the investigational arm is consistent with longer survival as compared to patients randomized to the control arm.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Prostatic disorders (excl infections and inflammations)
Study type	Interventional

Summary

ID

NL-OMON39174

Source
ToetsingOnline

Brief title
SYNERGY

Condition

- Prostatic disorders (excl infections and inflammations)

Synonym
Prostate Cancer

Research involving

Human

Sponsors and support

Primary sponsor: Novella Clinical
Source(s) of monetary or material Support: Teva Pharma BV

Intervention

Keyword: Cancer, Custirsen, First-Line, Prostate

Outcome measures

Primary outcome

survival

Secondary outcome

milestone Day 140 status.

Study description

Background summary

In the Phase 2 Study (OGX-011-03), patients who were randomized to receive custirsen in combination with first-line docetaxel/prednisone treatment had slower disease progression, resulting in an overall survival benefit when compared to patients who were randomized to receive first-line docetaxel/prednisone treatment alone.

Study objective

To ascertain whether the survival time distribution for patients randomized to the investigational arm is consistent with longer survival as compared to patients randomized to the control arm.

Study design

This will be a randomized, open-label, multicenter, international trial. Treatment will consist of docetaxel/prednisone/custirsen vs. docetaxel/prednisone.

Intervention

Custirsen

Study burden and risks

core study:
The possible side effects as mentioned in the appendix of the patient information, which are different depending on the arm which the patient is randomised to.

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

Subjects must meet ALL of the following criteria to be eligible for inclusion into the study:

1. Age >= 18 years on the date of consent.
2. Histological or cytological diagnosis of adenocarcinoma of the prostate.
3. Metastatic disease on chest, abdominal, or pelvic CT and/or bone scan.
4. Systemic chemotherapy indicated due to progression while on or after androgen ablative therapy defined as:
a. Progressive measurable disease: at least a 20% increase in the sum of the longest diameters of measurable lesions over the smallest sum observed -or- the appearance of one or more new lesions as assessed by CT scan during hormone ablation treatment. Measurable lesions are nodal or visceral soft-tissue lesions with nodal lesions >= 20 mm in diameter or visceral/soft-tissue lesions >= 10 mm in diameter (see Section 6.3.1.1).
OR
b. Bone Scan Progression: appearance of 2 or more new lesions on bone scan during hormone ablation treatment.
OR
c. Increasing serum PSA level: Two consecutive increases in PSA levels documented over a previous reference value obtained at least one week apart are required. If the third PSA value is less than the second, an additional fourth test to confirm a rising PSA is acceptable. A minimum starting value of 5.0 ng/mL is required for study randomization.
NOTE: Androgen ablative therapy may have included either medical or surgical castration.
5. Baseline laboratory values as stated below:
a. Creatinine 1.5 x upper limit of normal (ULN).
b. Bilirubin <= 1.1 x ULN (unless elevated secondary to conditions such as Gilbert*s disease).
c. SGOT (AST) and SGPT (ALT) <= 1.5 x ULN.
d. Castrate serum testosterone level (< 50 ng/dL-or-< 1.7 nmol/L).
6. Must be willing to continue primary androgen suppression with gonadotropin-releasing hormone (GnRH) analogues (either agonists or antagonists) throughout the study, unless treated with bilateral orchiectomy.
7. Adequate bone marrow function defined at screening as ANC >= 1.5 x 109 cells /L and platelet count >= 100 x 109 /L.
8. Karnofsky score >= 70%.
9. At least 28 days has passed since completing radiotherapy (exception for radiotherapy: at least 7 days since completing a single fraction of <= 800 cGy to a restricted field or limited-field radiotherapy to non-marrow bearing area such as an extremity or orbit) at the time of randomization.
10. At least 4 weeks have passed since receiving any investigational agent at the time of randomization.
11. Has recovered from any other therapy-related toxicity to <= grade 2, (except alopecia, anemia and any signs or symptoms of androgen deprivation therapy).

Exclusion criteria

Subjects meeting ANY of the following exclusion criteria will NOT be eligible for inclusion into the study:
Protocol OGX-011-11, Ver 13 Teva Clinical Study Protocol
1. Received any other cytotoxic chemotherapy as treatment for prostate cancer.

2. Received any cycling, intermittent or continuous hormonal treatment 28 days prior to randomization with the exception of the continuous GnRH analogues required in Inclusion Criteria #6.
3. Participated in a prior clinical study evaluating custirsen.
4. History of or current documented brain metastasis or carcinomatous meningitis, treated or untreated. (Brain imaging for asymptomatic patients is not required.)
5. Current symptomatic cord compression requiring surgery or radiation therapy. (Once successfully treated and there has been no progression, patients are eligible for the study.)
6. Active second malignancy (except non-melanomatous skin or superficial bladder cancer) defined as requiring anticancer therapy or at high risk of recurrence during the study.

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:	Recruitment stopped
Start date (anticipated):	18-08-2011
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	niet van toepassing
Generic name:	Custirsen

Ethics review

Approved WMO Date:	14-04-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-06-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	25-07-2011
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-09-2011
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-11-2011
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-03-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-03-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO	

Date:	11-04-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-08-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-02-2013
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-04-2013
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-01-2014
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2010-021011-16-NL
ClinicalTrials.gov	NCT01188187
CCMO	NL32952.000.11