A phase I/II trial of Cabazitaxel +/- Rhenium-188 HEDP in patients with metastatic castration resistant prostate cancer who progressed on or after a docetaxel containing treatment.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22536

Source
NTR

Brief title
ReCab study

Health condition

Patients with castration resistant metastatic prostate cancer to the bone.
Ossaal gemetastaseerd prostaatkanker patienten.

Sponsors and support

Primary sponsor: Meander Medical Center, Utrechtseweg 160, 3818ES Amersfoort, The Netherlands
Source(s) of monetary or material Support: Investigator driven trial

Intervention

Outcome measures

Primary outcome

Progression free survival. Progression is defined according to the recommendations of the Prostate Cancer Clinical Trials Working Group (Scher et al, JCO 2008, 26(7), 1148-59)

Secondary outcome

QoL score every (EORTC QlQ 30), pain score (VAS score), skeletal related events, Toxicity (NCI-CTC version 3) every three weeks.

Study description

Background summary

Prostate cancer is very common and often leads to bone metastases. Although initially most patients respond to androgen deprivation, after approximately 18 months the cancer will become hormone refractory leading to progressive disease. Since 2004 docetaxel became standard chemotherapy for men with metastatic CRPC leading to survival benefit. Several trials have shown evidence of the disease modifying potential of bone seeking radionuclides. Recent studies have shown an improvement of survival and quality of life when Rhenium-186 HEDP was given in high dosage or repeatedly. Recently results of our dose finding trial (XRP6976J/6213) shows that combined therapy with docetaxel and Rhenium-186 HEDP is generally well tolerated in patients with metastatic bone disease from prostate cancer. A phase II study (DOCET_L_04935) will be conducted using 3 cycles of docetaxel 75mg/m2 followed by Rhenium-188 HEDP , followed by another 3 cycles of docetaxel, followed by Rhenium-188 HEDP. Cabazitaxel is a promising new drug to be used for the treatment of metastatic castrate resistant prostate cancer (mCRPC) after progression on docetaxel therapy.
In this study, we build upon previous results and we aim to test whether the combination of cabazitaxel with repeated Rhenium-188 HEDP is feasible and leads to better PFS, OS and pain control compared to cabazitaxel alone in patients with mCRPC after progression of disease after first line docetaxel. We start with a phase I dose finding trial, immediately followed by a phase II trial if the envisaged schedule is feasible.

Study objective

In this study, we build upon previous results and we aim to test whether the combination of cabazitaxel with repeated Rhenium-188 HEDP is feasible and leads to better PFS, OS and pain control compared to cabazitaxel alone in patients with mCRPC after progression of disease after first line docetaxel. We start with a phase I dose finding trial, immediately followed by a phase II trial if the envisaged schedule is feasible.

Study design

The study will take about 2 years starting approximately at 01-02-2012.

Intervention

In the phase I part patients will recieve Rhenium-188 HEDP in combination with a dose finding schedule of Cabazitaxel (20 mg/m2 or 25 mg/m2). The feasible combination will be used in the following randomized phase II part of the study. Patients will be randomised between treatment with Cabazitaxel monotherapie or combination therapy with Cabazitaxel and Rhenium-188 HEDP.

Contacts

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Eligibility criteria

Inclusion criteria

1. mCRPC patients with documented disease progression:

A. If measureable: (RECIST) progression;

B. If non-measurable: documented rising PSA levels (at least 2 consecutive rises in PSA over a reference value taken at least 1 week apart) or appearance of new lesion.

2. Previous treatment with a docetaxel-containing regimen;

3. WHO performance status 0 or 1;

4. Life expectancy of at least 3 months;

5. Age > 18years;

6. Adequate renal function defined as serum creatinin ≤ 1.5 x ULN and/or calculated creatinin clearance 50ml/min;

7. Absolute neutrophil count (ANC) ≥ 1.5 x 109/L, platelet count ≥ 100 x 109/L;

8. Total bilirubin ≤ 1 x ULN, ALT, AST ≤ 2.5 x ULN;

9. Alkaline phosphatase < 10 x ULN;

10. Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial;

11. Written informed consent;

12. Bone metastases must show uptake of Tc-99m-HDP on bone scintigraphy;

13. Adequate hematological function defined as: Haemoglobin > 9 g/dl; Total White cell count >4.0 x 109/l; Platelet count >100 x 109/l;

14. Patients under LH-RH agonists must continue their treatment;

15. Prior hormonal therapy for prostate cancer, resulting in serum testosterone < 50ng/dl.

Exclusion criteria

1. Previous exposure to Rhenium -188- HEDP within 2 months;

2. Active uncontrolled bacterial, viral or fungal infection;

3. History of another malignancy within the last five years except adequately treated basal cell carcinoma of skin;

4. Organ allografts requiring immunosuppressive therapy;

5. Serious uncontrolled concomitant disease.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2012
Enrollment:	90
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL3085
NTR-old	NTR3233
Other	VCMO : R-11-46M
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Eur J Nucl Med Mol Imaging. 2011 Nov;38(11):1990-8. Epub 2011 Jul 27.
A phase I study of combined docetaxel and repeated high activity 186Re-HEDP in castration-resistant prostate cancer (CRPC) metastatic to bone (the TAXIUM trial).
van Dodewaard-de Jong JM, de Klerk JM, Bloemendal HJ, van Bezooijen BP, de Haas MJ, Wilson RH, O'Sullivan JM.