A randomised phase II study of repeated Rhenium-188 HEDP combined with Docetaxel versus Docetaxel alone in castration resistant prostate cancer (CRPC) metastatic to bone*

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To compare the effect of standard care (Docetaxel monotherapy) versus the combination of Docetaxel with Rhenium-188 HEDP for the treatment of patients with progressive castration resistant prostate carcinoma metastatic tot bone.

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

Summary

ID

NL-OMON39120

Source
ToetsingOnline

Brief title
Rhenium combined with Docetaxel in prostate cancer metastatic to bone

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
Prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bone metastases, Docetaxel, Prostate cancer, Rhenium-188 HEDP

Outcome measures

Primary outcome

To compare time to progression (clinical i.e. change of treatment required, or

Biochemical i.e. PSA) in men with progressive CRPC involving bone between

standard care of 3-weekly Taxotere 75mg/m2 (to maximum 10 cycles) VERSUS

3-weekly Taxotere 75mg/m2 + 2 infusions of Rhenium-188 HEDP

Secondary outcome

- To compare PSA response rates

- To compare overall survival

- To determine the effects of these two treatment regimens on pain response, in

patients with pain and quality of life.

Study description

Background summary

Prostate cancer is the most common cancer in men in Western Europe and about 30 percent of these patients will develop metastatic disease. The skeleton is involved in more than 80% of the patients with metastatic progression. These bone metastases are associated with severe pain, pathologic fractures, bone marrow insufficiency and spinal cord compression. First line treatment consists of androgen suppression. Although initially the majority of patients is responding to androgen deprivation, after an average of 18 months the cancer will become hormone refractory leading to progressive disease and high morbidity. The median survival in hormone refractory patients is about 12

months. Recent studies have shown not only a quality of life benefit but also for the first time a survival benefit for men treated with Docetaxel. In addition, patients are often treated with bone seeking radionuclides to palliate bone pain. Recent studies suggest a survival benefit and better quality of life for patients that are treated with the combination of Docetaxel en radionuclidetherapy.

Study objective

To compare the effect of standard care (Docetaxel monotherapy) versus the combination of Docetaxel with Rhenium-188 HEDP for the treatment of patients with progressive castration resistant prostate carcinoma metastatic tot bone.

Study design

This is a randomized phase II study comparing a schedule of repeated administration of the bone-seeking radionuclide, Re-188 HEDP combined with 3-weekly Taxotere (Optimum dose schedule to be determined by ongoing Phase 1 study) with the standard schedule of Taxotere 3-weekly for a maximum of 10 cycles. The experimental arm will consist of 3 cycles of Taxotere 75mg/m2 followed by a treatment of Rhenium-188 HEDP (MTD), followed by 3 further cycles of Taxotere 75mg/m2 followed by a second treatment of Rhenium-188 HEDP followed by a maximum of 4 further cycles of Taxotere. Patients for inclusion will have progressive prostate cancer and painful skeletal. Imaging (up to 8 weeks before treatment) and PSA measurement (3 assessments with at least 1 week interval) will be done at baseline to assess disease status and the extent of metastatic disease. The patients will be followed for 24 weeks after the last treatment. Disease status, palliative response and safety will be assessed during this study period.
Clinical outcome will be determined at 9, 12, 18 and 24 months after treatment, as well as hematology and clinical chemistry to assess chronic toxicity, if any. Survival data will be collected at 12, 18 and 24 months after the first treatment.

Intervention

Randomisation between:
- Docetaxel 75 mg/m2 3-weekly for a maximum of 10 cycles

and

- 3 cycles Docetaxel 75 mg/m2, followed by a gift Rhenium-188 HEDP, followed by 3 cycles Docetaxel 75 mg/m2, followed by a gift Rhenium-188 HEDP, followed by a maximum of 4 cyclesDocetaxel 75 mg/m2

Study burden and risks

Burden
- Patients in arm B will have two extra visits to the hospital (hospital stay 0.5 day)
- Additional bloodsamples: after the two cycles of rhenium (2x), during follow-up (4x) and in case the patient participates in a side study (optional): 3 times 9 ml. For the last no additional venapunctares are necessary, but blood will be drawn during a regular punction
- Patients will be asked to fill in questionnaires about quality of life

Risks
- The most important risk is hematological toxicity, especially leucopenia and trombocytopenia. However, the phase I trial has showed that the combination of Rhenium and Docetaxel is generally well tolerated and hematological toxicity is self limiting.

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

- Prostate carcinoma;- Bone metastases;- Hormone therapy resistent

Exclusion criteria

- Previous exposure to Rhenium or Docetaxel;- Bone marrow insufficiency

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):	31-08-2012
Enrollment:	88
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Rhenium-188 HEDP
Generic name:	Rhenium-188 HEDP

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

Ethics review

Approved WMO Date:	19-08-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-06-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-08-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-08-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-10-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-11-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	11-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-01-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-03-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-01-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2009-018044-18-NL
CCMO	NL31003.100.09