Randomized phase II/III study of Risedronate in combination with Docetaxel versus Docetaxel alone in patients with hormone refractory prostate cancer.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22637

Bron
Nationaal Trial Register

Verkorte titel
NePro

Ondersteuning

Primaire sponsor: Not applicable
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of phase II part is to assess the objective PSA response to treatment by serial measurements of serum PSA as defined by the "Bubley".

Primary objectives phase III study is to compare time to progression between concomitant and sequential use of docetaxel and risedronate, in combination with prednison.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

Clinical studies with mitoxantrone and clodronate showed a better pain reduction in patients with prostate cancer. Both in vitro and animal studies have shown that paclitaxel and biphosphonates act synergistically and prevent formation and progression of bone metastasis (breast cancer). This clinical trial studies the effect of risedronate and docetaxel in the treatment of hormone refractory prostate cancer.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Arm A. Docetaxel 75mg/m2 every 3 weeks. Every patient will receive prednison 5 mg bid.

Arm B. Docetaxel 75mg/m2 every 3 weeks plus 30 mg Risedronate once daily. Every patient will receive prednison 5 mg bid.

Treatment will be given until progression, or 10 courses. After progression Risedronate 30 mg od + prednisone 5 mg will be continued.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Histologically proven prostate adenocarcinoma;

2. Hormone refractory;

3. Continued elevated PSA for at least 6 weeks after discontinuation of anti-androgens prior to registration;

4. Last PSA level > 5 ng/ml;

5. Stable analgesic regimen for at least one week prior to registration;

6. Patients without surgical castration must continue on LHRH antogonists;

7. Adequate bone marrow, liver, renal funtion;

8. WHO 0-2.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous or concomitant use of biphosphonates;

2. Prior chemotherapy or radiotherapy within 4 weeks prior to treatment start;
3. Uncontrolled hypercalcemia;

4. Brain metastases;

5. Previous or concomitant malignancies;

6. Uncontrolled systemic disease of infection.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-12-2003
Aantal proefpersonen:	480
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	24-10-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL429
NTR-old	NTR469
Ander register	: EMC 03-146
ISRCTN	ISRCTN22844568

Resultaten

Samenvatting resultaten
N/A