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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22637

Source
NTR

Brief title
NePro

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary objectives phase II are to assess the toxicity profile, objective response (RECIST) and duration of PSA reponse.

Seondary objectives phase III study is to compare the following paramaters: PSA reponse (Nubley rate), PPI according to McGIll-Melzack toxicity profile, objective response (RECIST), duration of PSA response, survival

Study description

Background summary

N/A

Study objective

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.

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2003
Enrollment:	480
Type:	Actual

Ethics review

Positive opinion

Date:	24-10-2005
Application type:	First submission

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	NL429
NTR-old	NTR469
Other	: EMC 03-146
ISRCTN	ISRCTN22844568

Study results

Summary results
N/A