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

Submission date	Recruitment status	Prospectively registered
27/01/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
27/01/2006	Completed	Results
Last Edited	Condition category	Individual participant data
14/08/2009	Cancer	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr R de Wit

Contact details

Erasmus Medical Center Rotterdam Department of Medical Oncology P.O. Box 5201 Rotterdam Netherlands 3008 AE

Additional identifiers

Protocol serial number

NTR469; EMC 03-146

Study information

Scientific Title

Acronym

NePro

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical eithics committee

Study design

Multicentre randomised open label active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prostate Cancer

Interventions

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

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

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

- 1. Assess the objective PSA response to treatment by serial measurements of serum PSA as defined by the 'Bubley'.
- 2. Compare time to progression between concomitant and sequential use of docetaxel and risedronate, in combination with prednisone.

Key secondary outcome(s))

Compare the following parameters:

- 1. PSA response (Nubley rate)
- 2. PPI according to McGIll-Melzack toxicity profile
- 3. Objective response (RECIST)
- 4. Duration of PSA response
- 5. Survival

Completion date

01/01/2007

Eligibility

Key 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; last PSA level >5 ng/ml
- 4. Stable analgesic regimen for at least one week prior to registration
- 5. Patients without surgical castration must continue on LHRH antagonists
- 6. Adequate bone marrow, liver, renal function
- 7. WHO 0-2

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key 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

Date of first enrolment

15/12/2003

Date of final enrolment

01/01/2007

Locations

Countries of recruitment

Netherlands

Study participating centre
Erasmus Medical Center Rotterdam
Rotterdam
Netherlands
3008 AE

Sponsor information

Organisation

Erasmus Medical Centre (Netherlands)

ROR

https://ror.org/018906e22

Funder(s)

Funder type

Industry

Funder Name

Sanofi-Aventis B.V. (Netherlands)

Funder Name

Erasmus Medical Centre (Netherlands) (added 10/08/09)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration