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

Submission date
27/01/2006

Registration date
27/01/2006

Last Edited
14/08/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
15/12/2003

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

Age group
Adult

Sex
Male

Target number of participants
480

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)

Sponsor details
Postbus 2040
Rotterdam
Netherlands
3000 CA

Sponsor type
University/education

Website
http://www.erasmusmc.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration