

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/08/2009	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 risidronate, 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