ZEUS study.

No registrations found.

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

Summary

ID

NL-OMON23035

Source
Nationaal Trial Register

Brief title
ZEUS study

Health condition

Patients with high risk prostate cancer.

Sponsors and support

Primary sponsor: European Association of Urology
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

The primary outcome parameter is the proportion of patients who develop bone metastases during the study.

Secondary outcome

1. Time to first bone metastasis;

2. Overall survival;

3. Time to PSA doubling;

4. Safety;

5. On bone mineral density (sub study in selected centres) and

6. On biochemical markers of bone turnover (sub study in selected centers only).

Study description

Background summary

Zoledronic acid (Zometa®) is a third-generation nitrogen-containing bisphosphonate which has been approved in Europe and the US for the treatment of bone metastases (4mg Zoledronic acid iv/month) in a broad range of tumors and for the treatment of malignancy-related hypercalcaemia.

In animal models, bisphosphonates have been shown to reduce and even to prevent the development of bone metastases. The hypothetical mechanisms for this antitumor effect by bisphosphonates are

• The inhibition of osteoclastic bone resorption prevents the release of tumor-promoting growth factors from the bone matrix;

• Inhibition of the adhesion of tumor cells to bone matrix;

• Inducing tumor cell apoptosis
It is expected that in the present study Zometa® in addition to the prevention of bone metastases will show its potential in preventing hormone therapy induced bone loss.

Study objective

N/A

Intervention

Patients will be randomised between standard treatment plus Zometa® 4 mg infusions every 3 months for a total of 48 months or standard treatment only.

Contacts

Public
Christien Caris
[default]
The Netherlands
Scientific
Christien Caris
[default]
The Netherlands

Eligibility criteria

Inclusion criteria

1. Male patients aged 18+, ECOG = 0 (Karnofsky performance status > 90);

2. M0 prostate cancer patients who previously received local curative treatment (e.g. surgery, radiotherapy) or no local curative treatment. Duration between local curative treatment and starting of the study drug must not be longer than 6 months;

3. At least one of the following conditions must be present:

a. Gleason Score 8-10;

b pN+;

c. PSA equal to or higher than 20 ng/ml at diagnosis;

4. Patients receiving androgen deprivation by orchiectomy or administration of GnRH analogue ¡Ó anti-androgens or no androgen deprivation. Hormone therapy regimen will depend on standard medical management of prostate cancer patients, i.e. when corresponding to standard medical management, patients on hormone treatment at study entry can later be withdrawn and patients not on hormone treatment at study entry can later start with androgen deprivation.

Intermittent hormone treatment is allowed when corresponding to standard medical management.

Patients should not be under hormonal ablation for longer than 6 months before the first study drug infusion.

Neoadjuvant androgen deprivation is allowed as long as the duration between start of

androgen deprivation and start of study drug is no longer than 6 months;

5. Life expectancy of > 6 months;

6. Signed informed consent prior to initiation of any study procedure.

Exclusion criteria

1. Patients with known visceral metastasis or bone metastases in bone scan;

2. Prior treatment with bisposphonates;

3. Chemotherapy to treat prostate carcinoma;

4. Anti-androgen monotherapy is not allowed;

5. Use of other investigational drugs (drugs not marketed for any indication) within 6 months before start of study;

6. History of noncompliance to medical regimens and patients who are considered potentially unreliable or incapable of giving informed consent as judged by the investigator;

7. Serum creatinine > 3 mg/dl (265 ƒÝmol/L);

8. History of other malignant neoplasm within previous five years with exception of non-melanomatous skin cancer which has been satisfactorily treated;

9. Other known concurrent, severe medical disorder jeopardizing the life of the patient in the immediate future (myocardial infarction in previous six months, angina pectoris despite treatment, uncontrolled severe arterial hypertension, progressive cardiac or respiratory failure).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2004
Enrollment:	1300
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
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	NL317
NTR-old	NTR355
Other	: N/A
ISRCTN	ISRCTN66626762

Study results

Summary results

Wirth et al. Prevention of bone metastases in patients with high-risk non metastatic prostate cancer treated with Zoledronic Acid: Efficacy and safety results of the Zometa EUropean Study (ZEUS). Eur. Urol. 67 (2015) 482–491. http://dx.doi.org/10.1016/j.eururo.2014.02.014