Effectiveness of Zometa® treatment for the prevention of bone metastases in high risk prostate cancer patients. A randomized, open-label, multicenter study of the European Association of Urology (EAU) in Cooperation with the Scandinavian Prostate Cancer Group (SPCG) and the Arbeitsgemeinschaft Urologische Onkologie (AUO).

Protocol Number. CZOL446G DE08  Eudract Number 2004-001786-18

Timeline

• Start date recruitment: June 2004
• End date of recruitment: August 2007
• End date of study: December 2011
• Status: Two-year extended follow up completed, publised

In Brief

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 hypercalcemia. In animal models, bisphosphonates have been shown to reduce and even to prevent the development of bone metastases.

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.

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

Primary Outcome

The proportion of patients who develop bone metastases during the study.

Secondary Outcomes

1. Time to first bone metastasis;
2. Overall survival;
3. Time to PSA doubling;
4. Safety;
5. Bone mineral density (sub study in selected centres) and
6. Biochemical markers of bone turnover (sub study in selected centers only).

Please find the full description of the trial on the Nederlands Trial Register

Study Design

N = 1433
High risk* Prostate cancer
No history of bone disease

Randomisation

N = 716
Zometa 4mg IV
Every 3 months

N = 717
Control Group

End of Study

48 months or until first bone metastasis

* High risk prostate cancer

PSA at diagnosis ≥ 20 ng/ml or Gleason score 8-10 or pN+

All patients are on daily supplements of 500 mg Calcium and 400-500 IU of Vitamin D
Patient Recruitment

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Publications on patient recruitment


Study Publication


National Coordinators

Belgium: Prof. Thierry Roumeguere
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Finland: Prof. Teuvo Tammela
France: Prof. Clement-Claude Abbou
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