Alpharadin® (radium-223) is a novel alpha pharmaceutical in development for treatment of bone metastases. This new generation bone seeker emits alpha particles with high linear energy transfer (LET) alpha radiation with extremely short range, thus sparing bone marrow. These characteristics generate highly localized radiation zones which may inhibit tumour progression and induce pain relief. The aim of the study was to investigate if there is a pain relieving effect and a dose-response relationship after a highly localized radiation zones which may inhibit tumour progression and induce pain relief. The aim of the study was to investigate if there is a pain relieving effect and a dose-response relationship after a single dose of Alpharadin.

METHODS AND STUDY DESIGN

100 castration-refractory prostate cancer patients with painful bone metastases were randomised in a double-blind dose-ranging study. The primary efficacy endpoint was Pain Index based on a combination of the change in diary pain rating (VAS scale) and the change in analgesic consumption during a 16 weeks period. Pain and physical function were also measured using SF-36 (Brief Pain Inventory). Bone-ALP and safety were assessed.

The dose-related reduction of bone-ALP indicates a strong effect on the metastatic bone disease that develops as a result of the interaction between tumour cells and bone cells.

CONCLUSION

A single dose of Alpharadin (radium-223) exhibits a pain palliative effect in patients with painful bone metastases in castration-resistant prostate cancer patients. The most prominent effects were documented for the highest dose level, not only on pain relief but also on reduced bone-ALP. Up to 70% of patients experienced a pain response at week 4 in the two highest dose groups (50 and 100 kBq/kg b.w.).

At 8 weeks after injection there were 40, 65 and 71% responders (including only pain index categories 1 – 6) in the four dose levels: 5, 25, 50 or 100 kBq/kg b.w., respectively. Within each dose group, for the responders, a significant pain relief effect was observed in the patients’ diary VAS score. Median decrease were -15, -30, -26 and -22 mm and the p values were 0.01, 0.001, 0.0005 and <0.0001 respectively.

The study was to investigate if there is a pain relieving effect and a dose-response relationship after a single dose of Alpharadin.