Letters to the Editor

Oral ibandronate for the treatment of metastatic bone disease in breast cancer: efficacy and safety results from a randomized, double-blind, placebo-controlled trial

In their well-conducted randomized study on the efficacy of oral ibandronate to reduce the incidence of skeletal complications in breast cancer patients, Tripathy et al. [1] included a placebo group, even while acknowledging in their paper that bisphosphonates ‘are currently considered the standard of care for most patients’. It is unclear why it was considered ethical to withhold standard bisphosphonate treatment from 143 breast cancer patients.

The superiority of intravenous ibandronate over placebo has been well demonstrated in a recently published trial by the same group [2]. Although the concern I voiced about the ethics of including a placebo group in that study was published [3], no reaction from the authors was received. Perhaps the authors will now be inclined to clarify their position on this issue.

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References

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The original ibandronate trials were written and initiated before the approval and availability of bisphosphonates to prevent complications of bone metastases. At the time, these drugs were only used to treat hypercalcemia (and hypercalcemia was excluded from the ibandronate trial). During the course of these trials, results from other bisphosphonate trials did emerge, but only for lytic bone metastases, and the ibandronate trials included all bone metastases. The oral ibandronate trial opened after the intravenous trials, in 1996. Pamidronate was approved for lytic bone metastases in the USA in 1998. However, the ibandronate trials were also open in countries where these agents were still not available, and where they were available, the investigators at the individual center (after 1998) could use their discretion as to whom they would enroll—for example, patients with non-lytic bone metastases. Thus, the whole approach to treating bone metastases was evolving during the course of this trial. The follow-up, analysis and publication of the trial were longer than usual since the company that currently holds the license to the drug (Roche) acquired this drug from another company after the trial was completed.

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