Randomized Phase II trial of nintedanib, afatinib and sequential combination in castration-resistant prostate cancer

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ABSTRACT
Aims: The aim of this article was to evaluate afatinib (BIBW 2992), an ErbB family blocker, and nintedanib (BIBF 1120), a triple angiokinase inhibitor, in castration-resistant prostate cancer patients. Patients & methods: Patients were randomized to receive nintedanib (250 mg twice daily), afatinib (40 mg once daily [q.d.]), or alternating sequential 7-day nintedanib (250 mg twice daily) and afatinib (70 mg q.d. [Combi70]), which was reduced to 40 mg q.d. (Combi40) due to adverse events. The primary end point was progression-free rate at 12 weeks. Results: Of the 85 patients treated 46, 20, 16 and three received nintedanib, afatinib, Combi40 and Combi70, respectively. At 12 weeks, the progression-free rate was 26% (seven out of 27 patients) for nintedanib, and 0% for afatinib and Combi40 groups. Two patients had a ≥50% decline in PSA (nintedanib and the Combi40 groups). The most common drug-related adverse events were diarrhea, nausea, vomiting and lethargy. Conclusion: Nintedanib and/or afatinib demonstrated limited anti-tumor activity in unselected advanced castration-resistant prostate cancer patients.

type
journal paper/review (English)
date of publishing
2-2014
journal title
Future Oncol (10/2)
ISSN electronic
1744-8301
pages
219-31