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Capivasertib and fulvestrant, a new salvation for hormone receptor-positive breast cancer? A systematic review

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Objective: The treatment of estrogen receptor-positive (ER+) cancer has advanced significantly with the use of targeted therapies, but there are still cases in which therapy fails, therefore, carrying out a systematic review to address a treatment option for these cancers and visualize the importance of approval in Brazil. **Methodology:** We comprehensively searched the PubMed database for trials and phases I, II, and III that included treatment with capivasertib and fulvestrant in their papers. Our systematic review followed the PRISMA statement guidelines. **Results:** Cabivasertib in conjunction with fulvestrant is a new therapeutic modality for hormone-positive breast carcinomas refractory to conventional treatment because the mutability rate of these tumors is high and generates resistance to the various hormonal drugs already established on the market, such as tamoxifen and anastrozole. From the phase 2 FAKTION study, 140 patients were eligible for the study, in which 69 achieved dual treatment with a survival of 10.3 months compared with a placebo survival of 4.8 months. In the phase 3 CAPItello-291 study, 708 patients were eligible, and the overall survival was higher in the dual treatment group. Changes in AKT1 were found in 289, and the treatment resulted in a survival of 7.3 months compared with a survival of 3.1 months with a placebo. The adverse effects of the drugs were rash, diarrhea, hyperglycemia, kidney injury, vomiting, and atypical pneumonia due to indirect alteration of the immune system. **Conclusion:** It was evident that dual therapy capivasertib with fulvestrant is quite effective in the proposed treatment, even more so in patients with altered PI3K/AKT1/PTEN pathways, with efficacy and improvement in survival twice that of conventional treatment, and with less adverse effects comparable with the classic therapy. With this, it is safe to affirm the need for ANVISA to take the lead in this advancement in treatment and approve the treatment.

Keywords: breast cancer; estrogen receptor-positive; capivasertib; fulvestrant.