

Neratinib plus paclitaxel vs. trastuzumab plus paclitaxel in breast cancer

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While neratinib plus paclitaxel was not superior to trastuzumab plus paclitaxel as first-line treatment for ERBB2-positive metastatic breast cancer in terms of progression-free survival, the combination was associated with delayed onset and reduced frequency of central nervous system metastases, a finding that requires a larger study to confirm, according to an article published online by *JAMA Oncology*.

Metastatic ERBB2-positive breast cancer has a characteristic spread with most patients developing liver metastases and about half having poor prognosis with central [nervous system](#) involvement.

Ahmad Awada, M.D., of the Jules Bordet Institute, Brussels, and coauthors conducted a [randomized clinical trial](#) to examine progression-free survival in women with recurrent or metastatic ERBB2-positive breast cancer. They also examined secondary outcomes that included time to symptomatic or progressive central nervous system lesions and safety.

The NEfERT-T trial was conducted from 2009 through 2014 at 188 centers in 34 countries with 479 women, who were eligible if they had asymptomatic central nervous system lesions. The women were divided into two groups: 242 who received neratinib with paclitaxel and 237 who received trastuzumab plus paclitaxel.

Median progression-free survival was 12.9 months in both groups. However, the incidence of central nervous system recurrences was lower

and the time to central nervous system metastases was delayed with neratinib plus paclitaxel, according to the results.

Diarrhea and gastrointestinal effects, such as nausea and vomiting, were the main adverse events associated with neratinib plus paclitaxel, which was consistent with the safety profile previously documented for this combination, the authors report.

The authors note the study protocol did not include screening for central nervous system metastases but rather identified them on the presentation of symptoms, which means it is likely that central nervous system events were underestimated. The accrual goal of the study also was reduced from 1,200 to 480 patients, which the authors note was a limitation with regard to efficacy, along with the exclusion of patients with progressive or symptomatic central nervous system disease.

"Neratinib in combination with paclitaxel was not superior in terms of PFS [progression-free survival] compared with trastuzumab-[paclitaxel](#) in the first-line treatment of women with ERBB2-positive metastatic [breast cancer](#) but showed similar efficacy and may delay the onset and reduce the frequency of CNS [central nervous system] metastases," the authors conclude.

"The results presented herein by Awada et al are of sufficient interest to merit further investigation, preferably prospectively (with antidiarrheal prophylaxis), and in principle coupled with an extensive companion biomarker campaign designed to further characterize and classify those patients at highest risk for development of metastasis," writes Mark D. Pegram, M.D., of the Stanford School of Medicine, California, in a related editorial.

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