

Breast-conserving treatment without surgery not supported at this time

13 December 2019

Results from NRG Oncology's BR005 study show that breast-conserving treatment without surgery cannot be recommended, based on the study criteria of clinical complete response, radiological complete response (rCR)/near rCR, and negative tumor bed biopsies. These findings were presented at the 2019 San Antonio Breast Cancer Symposium, held December 10-14.

This phase II study, which opened in June 2017, was designed as a two-stage trial to assess the accuracy of tumor bed biopsies in predicting pathologic response in patients with clinical complete and radiological complete/near complete response after [neoadjuvant chemotherapy](#) to determine if they could avoid surgery. All patients had received chemotherapy for their [breast cancer](#), but had not yet had surgery. All underwent an image-guided [biopsy](#) after receiving chemotherapy. A total of 105 patients were enrolled from August 2017 through June 2019, with 98 being evaluable for [analysis](#). Accrual was temporarily closed for futility analysis on June 26, 2019, because 36 of the evaluable patients had residual disease at surgery, which actually met the numbers for the primary analysis. The negative predictive value of the biopsy was 77.5% (95%CI: 66.8% to 86.1%) which did not meet the pre-specified threshold of >90% required to support the feasibility of initiating a study in which [surgery](#) could be omitted.

"Further analysis including central review of tri-modality imaging and assessment of an imaging algorithm with and without the addition of biopsy are underway. Once these are combined with information on biologic subtypes, a new prediction model will be defined," according to Mark Basik, MD, from Jewish General Hospital, and lead investigator of the study.

More information: Basik M, Cecchini RS, De Los Santos JF, Umphrey HR, Julian TB, Mamounas EP, White J, Lucas PC, Balanoff C, Tan AR, Weber JJ, Edmonson DA, Brown-Glaberman UA,

Diego EJ, Teshome M, Matsen CB, Seaward SA, Wapnir IL, Wagner JL, Tjoe JA, Thompson AM, Wolmark N. Primary analysis of NRG-BR005, a phase II trial assessing accuracy of tumor bed biopsies in predicting pathologic complete response in patients with clinical/radiological complete response after neoadjuvant chemotherapy to explore the feasibility of breast-conserving treatment without surgery. San Antonio Breast Cancer Symposium 2019. Prog #: GS5-05.

Provided by NRG Oncology

APA citation: Breast-conserving treatment without surgery not supported at this time (2019, December 13) retrieved 16 June 2022 from <https://medicalxpress.com/news/2019-12-breast-conserving-treatment-surgery.html>

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