



**Susan G. Komen
Research Grants – Fiscal Year 2014**

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Randomized phase II trial of neoadjuvant cisplatin vs doxorubicin/ cyclophosphamide (“AC”) in women with newly diagnosed breast cancer and germline BRCA mutation

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Lead Organization: Dana-Farber Cancer Institute

Grant Mechanism: OG

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Public Abstract:

Due to the variable response rates reported with anthracycline-based chemotherapy in BRCA-associated breast cancers and the limited data using cisplatin in this population, it is important to directly compare cisplatin to standard chemotherapy in women with BRCA-associated breast cancer. That the results of a small single-arm cisplatin trial have led some to call for the addition or even the substitution of cisplatin or carboplatin to the adjuvant or neoadjuvant treatment of women with BRCA mutations seems premature and underscores the need for a prospective, randomized study.

To date, germline BRCA testing in women with newly diagnosed breast cancer has provided information used primarily for decisions about surgical choices (i.e. prophylactic mastectomies and bilateral salpingo-oophorectomies) and surveillance practices (e.g., breast MRI). Thus far, BRCA status has not influenced the choice of chemotherapy and the same regimens are used to treat breast cancer in BRCA mutation carriers and non-carriers. Therefore, genetic testing is often performed during or after chemotherapy administration. If, however, a non-standard chemotherapy regimen such as cisplatin is demonstrated to be superior to current standard regimens, management of newly diagnosed breast cancer would change since earlier BRCA testing would be necessary in order to select the optimal chemotherapy.

The primary goal of this study is to determine if there is at least a 25% greater pathologic complete response (pCR) rate after treatment with neoadjuvant cisplatin in women with newly diagnosed breast cancer and a germline BRCA mutation compared to treatment with doxorubicin/ cyclophosphamide (AC). The secondary aim is to compare the toxicities of preoperative cisplatin and doxorubicin/ cyclophosphamide chemotherapy in this population.

This grant provides funds for a clinical research specialist to facilitate the conduct of the trial at 8 collaborating academic medical centers.