Chemotherapeutic Agents - CCF IRB CC385 CASE 4107

Full Title
Clinical Study to Assess Entry of Chemotherapeutic Agents into Brain Metastases in Women with Breast Cancer.

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Objectives
To determine the concentration of certain chemotherapeutic drugs in brain metastases from breast cancer.

Eligibility
Inclusion
1. Age >18
2. Histologically or cytologically documented breast carcinoma with suspected or known parenchymal brain metastases for which surgical resection or biopsy is clinically indicated.
3. Karnofsky performance status _ 50
4. Life expectancy of _3 months
5. Patients must have the following laboratory parameters:
    - Absolute granulocyte count > 1500/mm3
    - Platelet count > 100,000 /mm3
    - Hemoglobin > 10 gm/dl
    - Creatinine < 1.5 x normal
    - Bilirubin (total) < 1.5 x normal
    - AST < 3 x normal
6. Off cytotoxic chemotherapy > 3 weeks (6 weeks for nitrosoureas, mitomycin-C).
7. Patients may continue hormone therapy and trastuzumab.
8. The patient's treating oncologist must agree that the patient would derive clinical benefit from receiving at least one of the following agents: capecitabine, cyclophosphamide, doxorubicin, gemcitabine, lapatinib, paclitaxel, trastuzumab, or vinorelbine
9. Off cranial radiation therapy > 4 weeks
10. Women of childbearing potential must have a negative urine or serum pregnancy test at screening.

11. All patients of reproductive potential must agree to use an effective method of contraception during the study and three months following termination of treatment.

Exclusions

1. Any toxicity > grade 2 felt to be from prior chemotherapy or radiation therapy at time of study entry
2. Patients who have received cytotoxic chemotherapy within 3 weeks (2 weeks for non-cytotoxic drugs [e.g., small molecule targeted drugs] and 6 weeks for nitrosoureas, mitomycin-C)
3. Patients who have received bevacizumab in past 60 days
4. Patients taking any experimental therapies
5. Severe cardiac insufficiency (NYHA III or IV), with uncontrolled and/or unstable cardiac or coronary artery disease.
6. Pregnant or lactating females
7. A history of noncompliance to medical regimens or inability or unwillingness to return for all scheduled visits.