B92-090

ABSTRACT

Study Proposal: **"A Clinical Trial to Evaluate the Worth of Tamoxifen in Conjunction with Lumpectomy and Breast Irradiation for the Treatment of Noninvasive Intraductal Carcinoma (DCIS) of the Breast"** 9213

This study will evaluate the effectiveness of Tamoxifen for preventing the occurrence of invasive and non-invasive cancers, both ipsilateral and contralateral, in patients with intraductal cancers treated by lumpectomy and breast irradiation. Following surgery and prior to irradiation, patients will be randomly assigned to one of two groups: (1) placebo for at least 5 years or (2) Tamoxifen for at least 5 years. There are four end points of interest in this study. The primary endpoint includes any subsequent invasive cancer in the ipsilateral or contralateral breast. Secondary end points are (1) noninvasive cancer of the ipsilateral or contralateral breast, (2) any cancer (invasive and noninvasive) of the ipsilateral breast, and (3) any cancer of the contralateral breast.

Navy Medicine

The conduct of this clinical trial in cancer therapy provides increased clinical and laboratory training opportunities for Navy personnel in the Hematology-Oncology, Internal Medicine, Nursing, Radiology, and Pathology Departments. Increased therapeutic benefit for DOD patients is the goal of this clinical investigation although such benefit cannot be assured, since that is one of the questions addressed by the clinical trial.

Adverse Reaction:

Adverse Reactions will be reported to the chairman, Committee for the Protection of Human Subjects via the clinical Investigation Department.

ENCLOSURE (4)