Under-reporting of Symptoms in Patients with Early Breast Cancer who have Received Tamoxifen Treatment for 2 to 3 years

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ABSTRACT

The Intergroup Exemestane Study (IEX20031-C13896 – 89107ET) is a randomized, double-blind trial comparing the benefits of tamopofin-like hormone therapy (HT) against placebo (P) in postmenopausal women with hormone receptor-dependent breast cancer. Baseline and postmenopausal women were randomized to HT vs. placebo (n=900). The analysis was restricted to a subset of 526 women who had reported symptoms at baseline and received at least one course of tamoxifen. Symptoms were scored using the Common Toxicity Criteria (CTC) 28.7. Symptom scores differed significantly (p<0.01) by country for hot flushes, weight gain, and cold sweats.

INTRODUCTION

The study has a 2x2 sub-protocol which includes assessment of oncologic symptoms. The primary endpoint is the incidence of new endometrial cancers. Secondary endpoints include objective measurement of recurrence-free survival, progression-free survival, and overall survival. This study is powered to detect a 30% difference in relapse-free survival between the two treatment groups.

METHODS

Methods for the analysis of symptoms include: (1) Use of a standardized tool to elicit symptoms; (2) Use of a symptom checklist to elicit symptoms; (3) Use of a symptom questionnaire to elicit symptoms; (4) Use of a symptom interview to elicit symptoms. The study has a 2x2 sub-protocol which includes assessment of oncologic symptoms. The primary endpoint is the incidence of new endometrial cancers. Secondary endpoints include objective measurement of recurrence-free survival, progression-free survival, and overall survival. This study is powered to detect a 30% difference in relapse-free survival between the two treatment groups.

RESULTS

The incidence of new endometrial cancers differed significantly (p=0.017) by country for hot flushes, weight gain, and cold sweats. The distribution of clinical symptom scores differed significantly (p<0.01) by country for hot flushes, weight gain, and cold sweats.

CONCLUSIONS

The analysis of symptoms in this study is consistent with previous reports. However, the difference in the distribution of symptom scores by country is significant. The study is powered to detect a 30% difference in relapse-free survival between the two treatment groups. This study is not powered to detect a 30% difference in relapse-free survival between the two treatment groups.