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Award Number: DAMD17-01-1-0193

TITLE: Soy and Tamoxifen for Breast Cancer Prevention in High Risk Pre-Menopausal Women

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REPORT DATE: October 2004

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	October 2004	Final (17 Sep 2001 - 16 Sep 2004)

4. TITLE AND SUBTITLE
Soy and Tamoxifen for Breast Cancer Prevention in High Risk Pre-Menopausal Women

5. FUNDING NUMBERS
DAMD17-01-1-0193

6. AUTHOR(S)
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 Words)

The current study is testing the feasibility and preliminary efficacy of soy supplementation to decrease risk of breast cancer by reducing breast density in individuals with ≥ 50% breast density on mammography and who are at elevated risk for breast cancer. One hundred women will be randomized to either 25 g/day of soy protein or placebo (milk protein). The randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using patient symptom scores and validated quality of life tools. Biological endpoints, including mammographic breast density, breast cytology, urinary estrogen metabolites, and blood serum biomarkers (IGF-1/IGF-BP 3), will be evaluated. Feasibility will be assessed by measuring the rate of recruitment, the percentage of women consuming at least 80% of the expected number of protein packets, and the dropout rate. Presently, 25 women have completed the study protocol and 24 women are on study treatment with the last women being scheduled to complete the study in January of 2005.

14. SUBJECT TERMS
Soy isoflavones, breast cancer prevention, mammographic breast density, quality of life

15. NUMBER OF PAGES
5

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

Table of Contents

Introduction

The PREVENT study is testing the feasibility and preliminary efficacy of soy supplementation to decrease risk of breast cancer in women who are at elevated risk for breast cancer based on the Gail model and have $\geq$ 50% breast density on mammography. One hundred women will be randomly assigned to 25 g/day of soy protein or a placebo (milk protein) for the 6-month study period. The randomized placebo controlled design allows for comparative toxicity and efficacy determinations using patient symptom scores, validated quality of life tools, and adverse event profiles. Biological endpoints, including changes in mammographic breast density, breast cytology, urinary estrogen metabolites, and blood serum biomarkers (IGF-1/IGF-BP 3, hormone levels) will be evaluated.

Accomplishments, Challenges and Future Goals

Since our last report a year ago, the recruitment of study participants increased dramatically through our collaboration with the San Francisco Mammography Registry (SFMR) and our continued outreach efforts into the community. In February of this year we sent out a direct mailing to 409 women meeting basic eligibility criteria from the SFMR database. A response post card was received from 26% of the 409 women, with an initial refusal rate of 34% from the responders. After phone contact with the women responding with interest to learn more about study participation, 27 women were scheduled for a screening clinic visit, 22 declined a clinic visit and 21 were found to be ineligible after the phone screen. In total, in the last year we have screened 126 women by phone of which 25 were found to be ineligible and 41 refused study participation.

We scheduled 51 screening visits and completed 41 of those visits. The visits not completed were due to a variety of reasons including cancelled visits due to irregular menses, changes in participant availability or failure of the participant to show. Of the 41 women who signed a consent form, 37 were randomized and started study treatment. The consented women who did not move onto randomization were due to either the failure to meet the breast density requirement or an intolerance of the study RUN-IN protein. At this date we have enrolled a total of 49 women.

Recruitment efforts were halted in July, in order to have all eligible women screened and enrolled by a date that allowed for completion of the study protocol by the end of the calendar year. The best efforts were made to maximize the number of women screened each week in the final months of accrual, with an average of 3 women consented a week for 3 consecutive months. Due to the study requirement to time visits to a specific part of the menstrual cycle and the somewhat unpredictability of these cycles, it was a significant challenge to schedule all interested women by the end of July. One participant who is an excellent study candidate due to her extremely dense breast tissue was unable to start the study protocol until the middle of August due to deviations in her menstrual cycle.

Another challenge of the last year has been the unscheduled contacts with participants in order to maintain their motivation to use the daily study protein. The ability of our study coordinator to keep motivation high in many women with differing personalities has resulted in keeping the mean adherence level above 80%. The primary goal of the remaining months of the study is to continue regular follow up with study participants by phone and in person to insure completion of the study protocol to the best of their ability.

Key Research Accomplishments

- 51 clinic Screening visits completed
- 37 randomization visits completed
- 32 3-month follow-up visits completed
- 17 close out (6-month) visit completed
- Implementation of a direct mailing for recruitment of women from the San Francisco Mammography Registry
- Digitization of mammography films and preparation of images for final analysis
- Data collected, reviewed for errors and entered into study database
- Data editing procedures completed for all data in the study database
- Biological samples (blood, urine, nipple aspirate and ductal lavage fluid) collected, processed and stored for later analysis

Reportable Outcomes

There are no reportable outcomes at the time of this report. Samples will be tested at the end of the study in order to reduce inter-assay differences. A description of the activities performed over the last year and plans for the completion of the research goals in the upcoming year can be found in an earlier section of this report

Conclusions

In the past year, we have overcome challenges in patient recruitment and successfully completed 17 study closeout visits. We were unable to meet our accrual goal of 100 participants due to the many challenges faced early in the funding period but we are confident in the quality of our data. The sample size of the current study is larger that of the only similar study, which Maskarinec et al published in 2003. In addition, the current study has controlled for the deficiencies listed by the authors of the previous study, which include variations in mammography technique and menstrual cycle timing. Due to the smaller than expected sample size we have decided to wait until all participants have completed the trial before analyzing any of the biological samples.