Award Number: DAMD17-01-1-0193

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

PRINCIPAL INVESTIGATOR: Jeffrey A. Tice, M.D.

CONTRACTING ORGANIZATION: University of California, San Francisco San Francisco, California 94143-0963

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

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

20050218 065

ÁD

REPORT DOCUMENTATION PAGE Form Approved OMB No. 074-0188 This report back to the back provides a survey to the resource of a survey and the	A		÷ .	、 ·		
Padd registing budget for the definition of subsets intered in page register, Holding hiles for research products, subsets and the page and the definition of the definit	REPORT DOCUMENTATION PAGE			0	Form Approved MB No. 074-0188	
Image blank Detroit Date S. REPORT TATE S. REPORT TYPE AND DATES COVERED Itame blank October 2004 Final (17 Sep 2001 - 16 Sep 2004) 4. TITLE AND SUBTITIE 5. FUNDING NUMBERS Soy and TEMOXIFEN for Breast Cancer Prevention in High Risk 5. FUNDING NUMBERS Fire-Menopausal Women 5. FUNDING NUMBERS P. FERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) 8. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Diffrey A. Tice, M.D. 8. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) San Francisco, California, San Francisco 8. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) San Francisco, California 94143-0963 10. 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 10. SUPPLEMENTARY NOTES 11. SUPPLEMENTARY NOTES 124. DISTRIBUTION / AVAILABUTTY STATEMENT Approved for Public Release, Distribution Unlimited 124. DISTRIBUTION / AVAILABUTTY STATEMENT Approved for Public Release, Distribution Unlimited 13. ABSTRACT IMAMENUM 200 Words) The current study is testing the feasibility and preliminary efficacy of soy supplementation to decrease risk of bric cancer by reducing breast densiby in individuals with > 50% breast densiby on mammographic breast densiby, bre 	Public reporting burden for this collection of info the data needed, and completing and reviewing reducing this burden to Washington Headquarte Management and Budget, Papenwork Reduction	rmation is estimated to average 1 hour per respons this collection of information. Send comments reg- ers Services, Directorate for Information Operations n Project (0704-0188), Washington, DC 20503	e, Including the time for reviewing in arding this burden estimate or any of and Reports, 1215 Jefferson Davis I	structions, searching end her aspect of this collect Highway, Suite 1204, A	xisting data sources, gathering and maintaining ction of information, including suggestions for rlington, VA 22202-4302, and to the Office of	
Itera bank October 2004 Final (17 Sep 2001 - 16 Sep 2004) ATTLE AMO SUBTITLE Soy and Tamoxifen for Breast Cancer Prevention in High Risk PAMD17-01-1-0193 Soy and Tamoxifen for Breast Cancer Prevention in High Risk PAMD17-01-1-0193 PAMD17-01-1-0193 F. FUNDORSING DAMD17-01-1-0193 PAMD17-01-1-0193 F. Authornal Substrate S. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) S. PERFORMING ORGANIZATION RAME(S) AND ADDRESS(ES) University of California, San Francisco San Francisco, California, San Prancisco S. PERFORMING ORGANIZATION RAME(S) AND ADDRESS(ES) J. S. PATTM MAGE MONTONING AGENCY REPORT NUMBER 10. SPONSORM/G / MONTORNO AGENCY NAME(S) AND ADDRESS(ES) 11. SUPPLEMENTARY NOTES 12. DISTINUTION CODI 11. SUPPLEMENTARY NOTES 12. DISTINUTION / AVAILABILITY STATEMENT AGENCY REPORT NUMBER 12. DISTINUTION / AVAILABILITY STATEMENT 12. DISTINUTION CODI AGENCY CALL AND ADDRESS (S) 13. ABSTRACT MAXIMUM 200 Wordd/ The current study is testing the feasibility and preliminary efficacy of soy supplementation to decrease nisk of br cancer by reducing breast density in individuals with 2 50% breast density on marmography and who are at elevated for breast cancer. One hundred women will be randomized to either 25 gday of soy protein or placebo (milk protei), cytology, unary estrogen metabolites, and blood se	1. AGENCY USE ONLY	2. REPORT DATE	3. REPORT TYPE AND	DATES COVER	ED	
4. THE AND SUBTINE Soy and TAMOXIÉE for Breast Cancer Prevention in High Risk Pre-Menopausal Women 5. FUNDING NUMBERS DAMD17-01-1-0193 6. AUTHORISJ Jeffrey A. Tice, M.D. 0. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of California, San Prancisco San Prancisco, California, San Prancisco San Prancisco, California, San Prancisco San Prancisco, California 94143-0963 0. PERFORMING ORGANIZATION MEPORT NUMBER 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of California, San Prancisco San Prancisco, California 94143-0963 10. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) 10. S. ARTY Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012 10. SPONSORING / MONITORING AGENCY NEPORT NUMBER 13. SUPPLEMENTARY NOTES 12. DISTRIBUTION / AVAILABUTY STATEMENT Approved for Public Release; Distribution Unlimited 12. DISTRIBUTION CODI (1. SUPPLEMENTARY NOTES 14. ABSTRACT (Maximum 200 Words) The current study is testing the feasibility and preliminary efficacy of soy supplementation to decrease risk of bur cancer One hundred women will be randomized to either 25 glday of soy pretein or placebo (milk protein). randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using pat symptom scores and validated quality of life tools. Biological endpoints, including marmographic breast density, be assessed by measuring the rate of recruitment, the precentage of women communing at least 80% of the expect number of protein packets, and the dropout rate. Presently, 25 women have completed the study protocol and 24 wom are on study treatment with the last women being scheduled to complete the study in January of 2005.	(Leave blank)	October 2004	Final (17 Sep	2001 - 16 Sep 2004)		
6. AUTHORIS) Jeffrey A. Tice, M.D. 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of California, San Francisco San Francisco, California 94143-0963 EMMit: jtice@medicine.ucsf.edu 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) 10. 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 11. SUPPLEMENTARY NOTES 12a. DISTRIBUTION / AVAILABULITY STATEMENT Approved for Public Release; Distribution Unlimited 12b. DISTRIBUTION CODE (mill protein) in dividuals with ≥ 50% breast density on mamography and who are at elevated for breast cancer. One hundred wormen will be randomized to either 25 g/day of soy protein or placebo (milk protein). randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using pat symptom scores and validated quality of life tools. Biological endpoints, including mamographic breast density, br cytology, urinary estrogen metabolites, and blood serum biomarkers (IGF-1/IGF-BP 3), will be evaluated. Feasibility be assessed by measuring the rate of recruitment, the percentage of women consuming at least 80% of the expect number of protein packets, and the dropout rate. Presently, 25 women have completed the study protocol and 24 wor 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 17. NUMBER OF PAGES Soy isoflavones, br	4. TITLE AND SUBTITLE Soy and Tamoxifen for Pre-Menopausal Women	Breast Cancer Preventi	on in High Risk.	5. FUNDING 1 DAMD17-01	<i>VUMBERS</i> -1-0193	
2. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) 8. PERFORMING ORGANIZATION University of California, San Francisco 8. PERFORMING ORGANIZATION San Francisco, California 94143-0963 8. PERFORMING ORGANIZATION EMMIR jtice@medicine.ucsf.edu 10. SPONSORING / MONITORING 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command 10. SPONSORING / MONITORING Fort Detrick, Maryland 21702-5012 11. SUPPLEMENTARY NOTES 11. SUPPLEMENTARY NOTES 12. DISTRIBUTION / AVAILABULITY STATEMENT Agency Takeward 12. DISTRIBUTION / AVAILABULITY STATEMENT Approved for Public Release; Distribution Unlimited 12. DISTRIBUTION / AVAILABULITY STATEMENT ABSTRACT (Maximum 200 Words/ 13. ABSTRACT (Maximum 200 Words/ The current study is testing the feasibility and preliminary efficacy of soy supplementation to decrease risk of bric cancer one hundred wormen will be randomized to either 25 g/day of soy protein or placebo (milk protein), randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using patient of the current study is testing the field of sub of the commen have completed the study protocol and 24 wor are on study treatment with the last women being scheduled to complete the study in January of 2005. 14. SUBJECT TEEMS 5 16. PRICE CODE Soy isoflavones, breast cancer prevention, mammographic	6 AUTHOR(S)	· · · · · · · · · · · · · · · · · · ·				
2. PERFORMING ORGANIZATION NAME(S) AND ADDRESS[ES) 2. PERFORMING ORGANIZATION University of California, San Francisco San Francisco, California 94143-0963 EMail: jtice@medicine.ucsf.edu 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS[ES) 10. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS[ES) 11. SUPPLEMENTARY MODES 11. SUPPLEMENTARY NOTES 12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited 12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited 13. ABSTRACT (Maximum 200 Words) The current study is testing the feasibility and preliminary efficacy of soy supplementation to decrease risk of bro cancer by reducing breast density in individuals with ≥ 50% breast density on mammography and who are at elevated for breast cancer. One hundred women will be randomized to either 25 g/day of soy protein or placebo (milk protein). randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using pat symptom scores and validated quality of life tools. Biological endpoints, including mammographic breast density, bre cytology, urinary estrogen metabolites, and blood serum biomarkers (IGF-1/IGF-BP 3), will be evaluated. Feasibility be assessed by measuring the rate of recruitment, the percentage of women norsuming at least 80% of the expect number of protein packets, and the dropout rate. Presently, 25 women have completed the study protocol and 24 wor are on study treatment with the last women being scheduled to complete the study in January of 2005. 14. SUBJECT TERMS Soy i sof lavones, breast Cancer prevention, mammographic breas	Jeffrey A. Tice, M.D.					
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) 2. PERFORMING ORGANIZATION University of California, San Francisco 8. PERFORMING ORGANIZATION San Francisco, California 94143-0963 10. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) 10. SPONSORING / MONITORING J.S. Army Medical Research and Materiel Command AGENCY NEPORT NUMBER Fort Detrick, Maryland 21702-5012 10. SPONSORING / MONITORING 11. SUPPLEMENTARY NOTES 12b. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited 12b. DISTRIBUTION code 13. ABSTRACT (Maximum 200 Words) 11b eresibility and preliminary efficacy of soy supplementation to decrease risk of brc cancer. One hundred women will be randomized to either 25 g/day of soy protein or placebo (milk protein). randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using pat symptom scores and validated quality of life tools. Biological endpoints, including mammographic breast density, be assessed by measuring the rate of recruitment, the percentage of women consuming at least 80% of the expect number of protein packets, and the dropout rate. Presently, 25 women have completed the study protocol and 24 wor are on study treatment with the last women being scheduled to complete the study in January of 2005. 14. SUBJECT TERMS 15. RECURITY CLASSIFICATION OF TREASE 20. LIMITATION OF ABSTR. Soy isoflavones, breast cancer prevention, mammographic breast 5		, · ·				
FMWIR: jtice@medicine.ucsf.edu 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) 10. SPONSORING / MONITORING AGENCY REPORT NUMBER U.S. ATMY Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012 10. SPONSORING / MONITORING AGENCY REPORT NUMBER 11. SUPPLEMENTARY NOTES 12b. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited 12b. DISTRIBUTION code 13. ABSTRACT (Maximum 200 Words) 12b. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited 12b. DISTRIBUTION code 14. AURACT (Maximum 200 Words) The current study is testing the feasibility and preliminary efficacy of soy supplementation to decrease risk of brc cancer by reducing breast density in individuals with ≥ 50% breast density on mamography and who are at elevated for breast cancer. One hundred women will be randomized to either 25 g/day of soy protein or placebo (milk protein). randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using pat symptom scores and validated quality of life tools. Biological endpoints, including mammographic breast density, be assessed by measuring the rate of recruitment, the percentage of women consuming at least 80% of the expect number of protein packets, and the dropout rate. Presently, 25 women have completed the study protocol and 24 wor 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. SECURITY CLASSIFICATION OF THIS PAGE 19. SECURITY CLASSIFICA	7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of California, San Francisco San Francisco, California 94143-0963			8. PERFORMING ORGANIZATION REPORT NUMBER		
9. SPONSONNIG / MONTORING AGENCY NAME(S) AND ADDRESS(ES) 10. 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 12b. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited 12b. DISTRIBUTION CODE 13. ABSTRACT (Maximum 200 Words) 12b. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited 12b. DISTRIBUTION code 13. ABSTRACT (Maximum 200 Words) 11. Supplementation to decrease risk of bre cancer by reducing breast density in individuals with ≥ 50% breast density on manmography and who are at elevated for breast cancer. One hundred women will be randomized to either 25 g/day of soy protein or placebo (milk protein). randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using pat symptom scores and validated quality of life tools. Biological endpoints, including mammographic breast density, bre cytology, urinary estrogen metabolites, and blood serum biomarkers (IGF-1/IGF-BP 3), will be evaluated. Feasibility be assessed by measuring the rate of recruitment, the percentage of women consuming at least 80% of the expect number of protein packets, and the dropout rate. Presently, 25 women have completed the study protocol and 24 wor 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. SECURITY CLASSIFICATION OF THIS PAGE 16. SECURITY CLASSIFICATION OF THIS PAGE <td>E-Mail: itice@medicine</td> <td>ucsf.edu</td> <td></td> <td></td> <td></td>	E-Mail: itice@medicine	ucsf.edu				
3. SPONSOMME NOW DAME AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012 11. SUPPLEMENTARY NOTES 12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited 13. ABSTRACT (Maximum 200 Words) The current study is testing the feasibility and preliminary efficacy of soy supplementation to decrease risk of bre cancer by reducing breast density in individuals with ≥ 50% breast density on mammography and who are at elevated for breast cancer. One hundred women will be randomized to either 25 g/day of soy protein or placebo (milk protein). randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using pat symptom scores and validated quality of life tools. Biological endpoints, including mammographic breast density, bre assessed by measuring the rate of recruitment, the percentage of women consuming at least 80% of the expect number of protein packets, and the dropout rate. Presently, 25 women have completed the study in January of 2005. 14. SUBJECT TERMS 15. NUMBER OF PAGES Soy isoflavones, breast cancer prevention, mammographic breast 5 17. SECURITY CLASSIFICATION OF ABESTRACT 18. SECURITY CLASSIFICATION OF ABESTRACT				10.000000		
U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012 11. SUPPLEMENTARY NOTES 12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited 12b. DISTRIBUTION code 13. ABSTRACT (Maximum 200 Words) 12b. 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. One hundred women will be randomized to either 25 g/day of soy protein or placebo (milk protein). randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using pat symptom scores and validated quality of life tools. Biological endpoints, including mammographic breast density, bre cytology, urinary estrogen metabolites, and blood serum biomarkers (IGF-1/IGF-BP 3), will be evaluated. Feasibility be assessed by measuring the rate of recruitment, the percentage of women consuming at least 80% of the expect number of protein packets, and the dropout rate. Presently, 25 women have completed the study protocol and 24 won 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 17. SECURITY CLASSIFICATION OF REPORT 18. SECURITY CLASSIFICATION OF THIS PAGE 19. SECURITY CLASSIFICATION OF ABSTRACT	9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)			AGENCY REPORT NUMBER		
11. SUPPLEMENTARY NOTES 12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited 13. ABSTRACT (Maximum 200 Words) The current study is testing the feasibility and preliminary efficacy of soy supplementation to decrease risk of breact cancer. One hundred women will be randomized to either 25 g/day of soy protein or placebo (milk protein). randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using path symptom scores and validated quality of life tools. Biological endpoints, including mammographic breast density, breast density, unlary estrogen metabolites, and blood serum biomarkers (IGF-1/IGF-BP 3), will be evaluated. Feasibility be assessed by measuring the rate of recruitment, the percentage of women consuming at least 80% of the experiment of protein packets, and the dropout rate. Presently, 25 women have completed the study protocol and 24 wom are on study treatment with the last women being scheduled to complete the study in January of 2005. 14. SUBJECT TERMIS 15. NUMBER OF PAGES Soy is of lavones, breast cancer prevention, mammographic breast density, quality of life 1 17. SECURITY CLASSIFICATION OF ABSTRACT 18. SECURITY CLASSIFICATION OF ABSTRACT 17. SECURITY CLASSIFICATION OF ABSTRACT 20. LIMITATION OF ABSTRACT	U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012					
13. ABSTRACT (Maximum 200 Words) The current study is testing the feasibility and preliminary efficacy of soy supplementation to decrease risk of breact cancer by reducing breast density in individuals with ≥ 50% breast density on mammography and who are at elevated for breast cancer. One hundred women will be randomized to either 25 g/day of soy protein or placebo (milk protein). randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using pat symptom scores and validated quality of life tools. Biological endpoints, including mammographic breast density, bre cytology, urinary estrogen metabolites, and blood serum biomarkers (IGF-1/IGF-BP 3), will be evaluated. Feasibility be assessed by measuring the rate of recruitment, the percentage of women consuming at least 80% of the expect number of protein packets, and the dropout rate. Presently, 25 women have completed the study protocol and 24 wor are on study treatment with the last women being scheduled to complete the study in January of 2005. 14. SUBJECT TERMS Soy i soflavones, breast cancer prevention, mammographic breast 5 16. NUMBER OF PAGES 5 16. PRICE CODE 17. SECURITY CLASSIFICATION OF ABSTRICT 18. SECURITY CLASSIFICATION OF ABSTRICT 18. SECURITY CLASSIFICATION OF THIS PAGE 19. SECURITY CLASSIFICATION OF ABSTRICT	12a. DISTRIBUTION / AVAILABILI Approved for Public Re	TY STATEMENT	limited		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 for breast cancer. One hundred women will be randomized to either 25 g/day of soy protein or placebo (milk protein). randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using pat symptom scores and validated quality of life tools. Biological endpoints, including mammographic breast density, bre cytology, urinary estrogen metabolites, and blood serum biomarkers (IGF-1/IGF-BP 3), will be evaluated. Feasibility be assessed by measuring the rate of recruitment, the percentage of women consuming at least 80% of the expect number of protein packets, and the dropout rate. Presently, 25 women have completed the study protocol and 24 wom are on study treatment with the last women being scheduled to complete the study in January of 2005. 14. SUBJECT TERMS 15. NUMBER OF PAGES Soy i soflavones, breast cancer prevention, mammographic breast 5 17. SECURITY CLASSIFICATION OF ABSTRACT 18. SECURITY CLASSIFICATION OF ABSTRACT 06 REPORT 18. SECURITY CLASSIFICATION OF ABSTRACT						
The current study is testing the feasibility and preliminary efficacy of soy supplementation to decrease risk of breact cancer by reducing breast density in individuals with ≥ 50% breast density on mammography and who are at elevated for breast cancer. One hundred women will be randomized to either 25 g/day of soy protein or placebo (milk protein). randomized placebo controlled design will allow for comparative toxicity and efficacy determinations using pat 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 be assessed by measuring the rate of recruitment, the percentage of women consuming at least 80% of the expect number of protein packets, and the dropout rate. Presently, 25 women have completed the study protocol and 24 wom 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 5 16. PRICE CODE 17. SECURITY CLASSIFICATION OF ABSTRACT 18. SECURITY CLASSIFICATION OF ABSTRACT 20. LIMITATION OF ABSTRACT	13. ABSTRACT (Maximum 200 W	lords)			<u> </u>	
14. SUBJECT TERMS 15. NUMBER OF PAGES Soy isoflavones, breast cancer prevention, mammographic breast 5 density, quality of life 16. PRICE CODE 17. SECURITY CLASSIFICATION OF REPORT 18. SECURITY CLASSIFICATION OF THIS PAGE 19. SECURITY CLASSIFICATION OF ABSTRACT 20. LIMITATION OF ABSTRACT	The current study is testing cancer by reducing breast de for breast cancer. One hund randomized placebo contro symptom scores and validat cytology, urinary estrogen m be assessed by measuring number of protein packets, a are on study treatment with t	the feasibility and preliminar ensity in individuals with $\geq 50\%$ red women will be randomized lled design will allow for con ed quality of life tools. Biologi netabolites, and blood serum b the rate of recruitment, the per nd the dropout rate. Presently he last women being scheduled	y efficacy of soy sup breast density on ma to either 25 g/day of s mparative toxicity an cal endpoints, includir biomarkers (IGF-1/IGF ercentage of women of y 25 women have con d to complete the stud	plementation mmography a soy protein or d efficacy de ng mammogra -BP 3), will b consuming at pleted the stu ly in January o	to decrease risk of breast and who are at elevated risk placebo (milk protein). The terminations using patient aphic breast density, breast e evaluated. Feasibility will least 80% of the expected udy protocol and 24 women of 2005.	
14. SUBJECT TERMS 15. NUMBER OF PAGES Soy isoflavones, breast cancer prevention, mammographic breast 5 density, quality of life 16. PRICE CODE 17. SECURITY CLASSIFICATION OF REPORT 18. SECURITY CLASSIFICATION OF THIS PAGE 19. SECURITY CLASSIFICATION OF ABSTRACT 20. LIMITATION OF ABSTRACT						
Soy isoflavones, breast cancer prevention, mammographic breast 5 density, quality of life 16. PRICE CODE 17. SECURITY CLASSIFICATION OF REPORT 18. SECURITY CLASSIFICATION OF THIS PAGE 19. SECURITY CLASSIFICATION OF ABSTRACT 20. LIMITATION OF ABSTRACT	14. SUBJECT TERMS				15. NUMBER OF PAGES	
17. SECURITY CLASSIFICATION OF REPORT 18. SECURITY CLASSIFICATION OF THIS PAGE 19. SECURITY CLASSIFICATION OF ABSTRACT 20. LIMITATION OF ABSTRACT	Soy isoflavones, breas density, quality of li	st cancer prevention, m lfe	ammographic brea	st	5 16. PRICE CODE	
OF REPORT OF THIS PAGE OF ABSTRACT	17. SECURITY CLASSIFICATION	18. SECURITY CLASSIFICATION	19. SECURITY CLASSIF		20. LIMITATION OF ABSTRACT	
	OF REPORT	OF THIS PAGE	OF ABSTRACT			
Unclassified Unclassified Unlimited		Unclassified	Unclassif:	Led	Unlimited	

Prescribed by ANSI Std. Z39-18 298-102

Table of Contents

Cover
SF 298
ntroduction1
Body1
Key Research Accomplishments2
Reportable Outcomes2
Conclusions2

•

4

•

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.

1

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.