

97405: Randomized Study of Soy Protein and Effexor™ on Vasomotor Symptoms of Men with Prostate Cancer

OBJECTIVES

Primary Protocol Objective

Assess the effect of soy and Venlafaxine (Effexor XR™) on the hot flash symptom severity score in men receiving hormonal manipulation treatment for prostate cancer

Secondary Protocol Objective

Assess the effect of soy and Effexor XR™ on quality of life in men receiving hormonal manipulation treatment for prostate cancer
Monitor and assess participant drop out rate

Eligibility

- Histologic documentation of prostate cancer, any stage
- Life expectancy of \geq nine months
- Prior or current androgen deprivation for treatment or control of prostate cancer to include:
 - Bilateral Orchiectomy
 - LHRH agonist (with or without antiandrogen therapy) ie: leuprolide (Lupron), goserelin (Zoladex), bicalutamide (Casodex), flutamide (Eulexin), or similar agents
 - Chemotherapy
 - Radiation (Patients may undergo concurrent radiation therapy to the prostate, prostate + seminal vesicles, and/or pelvis).
- Participant report of hot flash frequency of an average of four or more per day, as defined by sweating, flushing, sensation of warmth, night sweats (Average of 28 per week)
- Participants report of overall hot flash severity as moderate to severe
- Age \geq 21
- No allergies to soy or dairy products
- No current use of SSRIs, SNRI's, MAOIs
- No uncontrolled hypertension (160/90) or Greater than Class I American Heart Association functional capacity
- No history of mania, hypomania, bipolar disorder, or anorexia nervosa
- No history of seizures
- Adequate hepatic function (total bilirubin \leq 2) AST (SGOT) \leq 2 x institutional ULN)
- Must have a telephone
- Signed protocol-specific Informed Consent
- Participant must be willing to discontinue and/or avoid consuming soy foods or soy based supplements during study participation
- Patients should maintain same treatment and medications throughout entire study.

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Exclusion

- Anticipated changes in hormone treatment regimen, example: discontinuation of current chemotherapy or anticipating surgery
- Concurrent antidepressant therapy
- History of intolerance to venlafaxine
- Recent (within 14 days) use of venlafaxine (Effexor™), monoamine oxidase inhibitor, SSRI (selective serotonin reuptake inhibitor), or SNRI (selective norepinephrine reuptake inhibitor)
- History of seizure disorder
- Current use of medication to relieve hot flashes

Treatment schedule

Pre-study period (7 days) Candidates who are screened during a clinic visit and are eligible and willing to participate in the study, will be asked to complete the informed consent form at that visit, if possible. Patients signing the informed consent form will be asked to complete a vasomotor symptom diary for the next 7 days to document their baseline level of hot flashes. This week long period will also enable study personnel to determine if the patient is able to comply with completing the diary correctly during the entire 7 day period. Candidates experiencing difficulty in completing the diary correctly and/or completely will be counseled again in correct diary completion, and will be asked to complete a second 7 day vasomotor symptom diary to see if their recording of vasomotor symptoms improves. At the end of the second 7 day period, if the patient still has not completed the diary correctly and/or completely, the candidate will not progress to the intervention phase of the study and will be dropped.

The pre-study hot flash/flush symptom diary does not have to start on a Sunday.

The candidate must have an average of four or more hot flashes per day (i.e., 28 or more hot flashes for the week) and must report that his symptoms were moderate to severe. Candidates reporting fewer hot flushes will be deemed ineligible.

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Baseline After the 7 day baseline record of hot flashes, participants are randomly assigned, in a blinded fashion, to (1) Effexor XR™ 75mg po qAM and casein powder (20 gms) 1 packet/day; or (2) placebo pill po qAM and soy protein powder (20 gms with 160 mg isoflavones) 1 packet/day; or (3) Effexor XR™ 75mg po qAM and soy protein powder (20 gms with 160 mg isoflavones) 1 packet/day; or (4) placebo pill po qAM and casein powder placebo (20 gms) 1 packet/day.

The participant will be issued a supply of study powder, pills and vasomotor symptom diaries at the participating institutions discretion. During the study period, participant will take one pill and consume one packet of study powder each day.

Sunday Participants will be instructed to begin their study treatments on a Sunday in order to make it easier to complete the symptom diaries. Participants will be instructed to document symptoms in the diary each day and to indicate if they took their pill and study powder each day.

Week 2 The participant will be contacted by telephone to complete forms and check compliance. Patients should be advised to have blood pressure checked and report result to research personnel. Study coordinators will evaluate how he is doing in completing the diaries, to see if he has any questions about the study powder and pills, and to encourage compliance.

Week 4 The participant will be contacted by telephone to complete forms and check compliance. Patients will also be asked to return their 4 week Hot Flash Symptom and Adherence Diaries to the study coordinators.

Week 8 The participant will be contacted by telephone to complete forms and check compliance. Participants will also be asked to return their 8 week Hot Flash symptom and Adherence Diaries to the study coordinators.

Week 12 Patients will come to the clinic to be weighed and have their blood pressure measures. They will be asked to return their remaining powders, pill bottle, pills, and all of their remaining symptom diaries. They should be provided with enough pills to complete the taper during week 13.

Week 13 Patients will be instructed to taper their pills EffexorXR™ - / Placebo to one every other day for 1 week.

Agent Ordering and Distribution

Following patient registration, Biologics, Inc will be notified through the on-line registration process. Biologics will contact the site directly to obtain specific shipping information. All treatment required for the participant to complete the study will be delivered to the site in one shipment.

Administration

Effexor XR™ / Placebo is a tablet to be taken by mouth every morning through week 12.

EffexorXR™ /Placebo will be tapered to one pill every other day for week 13.

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STUDY PARAMETERS

Physical exam and lab tests required within 3 months of registration.

Study Measure	Pre-study Period	Baseline	Week 2 Telephone contact	Week 4 Telephone contact	Week 8 Telephone contact	Week 12/13 Clinic contact
Physical Exam	X ^A					
Hot Flash Symptom Diary (Appendix A)	X ^B					
Hot Flash Symptom and Adherence Diary (Appendix B)		X	X	X	X	X
Soy Food Questionnaire (Appendix C)		X				
Toxicity Assessment Sheet (Appendix K)		X	X	X	X	X
Fact-P (Appendix F)		X				X
Medications & Supplement Form (Appendix E)		X	X	X	X	X
Total Bilirubin (Appendix H)	X ^A					
SGOT (AST) (Appendix H)	X ^A					
Height (Appendix H)		X				
Weight (Appendix H)		X				X
Blood Pressure (Appendix H)		X	X ^C			X

(A) Must be completed within the last 3 months.

(B) Must be completed in a 7 day time period.

(C) Patient needs to have blood pressure monitored and results reported to research personnel.

- * **Initial labs to be drawn at baseline: Total Bilirubin, SGOT**
- * **Study medication is provided free of charge.**
- * **Upon patient registration, Biologics will receive notification to initiate shipment of study drug.**