

CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

1/14/2011  
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N07C2: The Use of Wisconsin Ginseng (*panax quinquefolius*) to Improve Cancer-Related Fatigue: A Randomized, Double-Blind, Placebo-Controlled Phase III Study

**To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.**

Has the patient ever been on a prior study entered through this Registration Office?  Yes  No

If yes: Prior study number \_\_\_\_\_; prior patient study ID number \_\_\_\_\_

Registration date (date on) (mm/dd/yyyy) ___/___/_____
Patient study ID number (provided at time of Reg/Random) _____
NCCTG member (participant sponsor) _____
NCCTG treating location _____
NCCTG treating physician _____
Institution patient number (local subject number) _____
IRB approval date (mm/dd/yyyy) ___/___/_____
<u>Person Completing Form:</u>
Last Name: <b>(print)</b> _____ First Name: <b>(print)</b> _____
Phone: _____ Fax: _____ Email: _____

Patient initials (last, first, middle) _____ (For Mayo Rochester patients, include first four letters of last name.)	Race (check all that apply)
Gender (check one) <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	<input type="checkbox"/> White
Date of birth (mm/dd/yyyy) ___/___/_____	<input type="checkbox"/> Black or African American
Zip code _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
Country of Residence _____	<input type="checkbox"/> Asian
	<input type="checkbox"/> American Indian or Alaska Native
	<input type="checkbox"/> Not reported: Patient refused or not available
	<input type="checkbox"/> Unknown: Patient unsure
Method of payment (check one)	Ethnicity (check one)
<input type="checkbox"/> PI (Private Insurance)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MRP (Medicare and Private Insurance)	<input type="checkbox"/> Not reported: Refused or data not available
<input type="checkbox"/> MD (Medicaid)	<input type="checkbox"/> Unknown: Unsure of their ethnicity
<input type="checkbox"/> MM (Medicaid and Medicare)	
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	
<input type="checkbox"/> MV (Veterans Sponsored)	
<input type="checkbox"/> SP (Self pay [no insurance])	
<input type="checkbox"/> NP (No means of payment [no insurance])	
<input type="checkbox"/> OTH (Other)	
<input type="checkbox"/> UNK (Unknown)	

Patient study ID number \_\_\_\_\_

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

**Required Characteristics**

Yes No NA

≥ 18 years of age. Age = _____.	___ ___
Men or women with a history of cancer-related fatigue as defined by an average score ≥4 over the past 30 days on the numeric analogue scale (1-10) (Linear Analogue Scale Fatigue Question 1; Appendix II). Fatigue Score = _____.	___ ___
The presence of fatigue ≥1 month prior to randomization.	___ ___
ECOG performance score 0, 1, 2. PS = _____.	___ ___
Histologic or cytologic proven cancer other than brain cancer or CNS lymphoma, undergoing curative intent therapy (including anti-hormonal therapies such as tamoxifen or leuprolide) or those having completed curative intent therapy who were diagnosed within the past 2 years. <b>Note:</b> If a patient is receiving treatment for their disease such as chemotherapy, targeted therapies, immunotherapy therapy or radiation therapy then, the patient must have completed ≥1 cycle of chemotherapy, targeted therapy, or ≥1 week of radiation treatment.	___ ___
Laboratory values obtained prior to randomization.	___ ___
<ul style="list-style-type: none"> <li>Hgb ≥11 (must be obtained ≤30 days; patients must not be transfused ≤30 days to meet this criterion). Hgb date ___/___/____. Hgb = _____.</li> </ul>	___ ___
<ul style="list-style-type: none"> <li>Creatinine ≤ 1.2 x UNL (must be obtained ≤180 days prior to randomization). Creatinine date ___/___/____. Creatinine = _____. UNL = _____.</li> </ul>	___ ___
<ul style="list-style-type: none"> <li>AST (SGOT) or ALT (SGPT) ≤ 1.5 x UNL (must be obtained ≤180 prior to randomization). <b>Which was done?</b> ___ AST (SGOT) date ___/___/____. AST (SGOT) = _____. UNL = _____. ___ ALT (SGPT) date ___/___/____. ALT (SGPT) = _____. UNL = _____. Both → Complete AST (SGOT) and ALT (SGPT) fields above</li> </ul>	___ ___
Negative pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. Not a woman of childbearing potential ( <i>check NA</i> ) vs. negative pregnancy test date ___/___/____	___ ___
Ability to complete patient questionnaires alone or with assistance.	___ ___
Controlled: <ul style="list-style-type: none"> <li>Pain (≤4 on Linear Analogue Scale Question 3 – Appendix II) Pain Score = _____</li> <li>Insomnia (≤4 on Linear Analogue Scale Question 2 – Appendix II) Insomnia Score = _____</li> </ul>	___ ___
Willingness to provide blood/saliva samples for correlative studies. <b>Note:</b> These samples are only required for those not receiving active treatment for their disease. Active treatment is defined as chemotherapy, radiation therapy, or immunotherapy, not anti-hormone therapy such as tamoxifen, aromatase inhibitors or leuprolide. If receiving active treatment for disease ( <i>check NA</i> ).	___ ___

All responses in above section must be “Yes” unless specified as “NA.”

**Contraindications**

Yes No NA

Hypersensitivity to ginseng.	___ ___
Prior use of ginseng capsules for fatigue in the past year. <b>Note:</b> Prior use of teas or drinks containing ginseng is allowed, however, patients will be asked to avoid these beverages while on the study.	___ ___
Uncontrolled hypertension on more than one occasion (diastolic blood pressure > 100, systolic > 160) measured ≤90 days prior to randomization.	___ ___
Currently using any other pharmacologic agents or nonpharmacologic interventions to specifically treat fatigue including psychostimulants, antidepressants, acupuncture, etc. <b>Note:</b> Antidepressants used to treat items other than fatigue (such as hot flashes) are allowed if the patient has been on a stable dose for ≥1 month and plans to continue for ≥1 month. Erythropoietin agents to treat anemia are allowed. Exercise is allowed.	___ ___
Known brain metastasis or primary CNS malignancy.	___ ___
Chronic systemic steroid use (including CHOP therapy or as part of any regular cancer treatment, however, steroids used as prophylaxis for nausea and vomiting are allowed). To prevent rash with Alimta, low dose dexamethasone will be allowed.	___ ___
Diabetes Type I or II (defined by being on oral hypoglycemics or insulin).	___ ___

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**Contraindications – (continued)**

	Yes	No	NA
Psychiatric disorder such as severe depression, manic depressive disorder, obsessive compulsive disorder or schizophrenia. (Defined per medical history).	___	___	___
≤4 weeks from major surgery to randomization, including any procedure that requires general anesthetic.	___	___	___
Any of the following: <ul style="list-style-type: none"> <li>• Pregnant women</li> <li>• Nursing women</li> <li>• Women of childbearing potential who are unwilling to employ adequate contraception</li> </ul>	___	___	___
Pain requiring opioid pain medication, however, over the counter analgesics such as Tylenol or ibuprofen are allowed.	___	___	___
Use of full dose of anticoagulant therapy (Exception: 1 mg/day of Coumadin for preventing catheter clots is allowed).	___	___	___
Use of MAO inhibitors.	___	___	___
Planning to start or complete any type of cancer therapy during the 8 week, double blind, course of the study, once randomized on the study. <b>Note:</b> If not currently getting treatment, no chemotherapy agents ≤ 21 days prior to randomization. Combination treatment regimens that have components ending at different times are allowed, as long as any part of the initially started treatment continues through the double blind portion of the study.	___	___	___
Malnutrition, active infection, significant pulmonary disease and cardiovascular disease as determined by the physician, as they could impact fatigue.	___	___	___
Use of any over the counter herbal/dietary supplement marketed for fatigue or energy (for example, products containing any type of ginseng, rhodiola rosea, high doses of caffeine, guarana, or anything called an “adaptogen”).	___	___	___
Uncontrolled nausea or vomiting or any symptom that would prevent the ability to comply with daily oral ginseng/placebo treatment.	___	___	___
Uncontrolled thyroid disorder.	___	___	___
Currently receiving single agent on blinded placebo controlled treatment trials.	___	___	___

**All responses in above section must be “No.”**

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be mm/dd/yyyy.

	Yes	No	NA
A mandatory translational research component is part of this study for patients NOT receiving chemotherapy or radiation therapy. Patients not receiving chemotherapy or radiation therapy must agree to do both the saliva and the blood sampling to participate. There will be an option to select if the patient is to be registered onto this component (Section 14.0). <ul style="list-style-type: none"> <li>• Patient is receiving active treatment and will not provide blood/saliva for research testing (<i>check NA</i>).</li> <li>• Patient is not receiving active treatment and will provide blood/saliva for research testing</li> </ul>	___	___	___
Consent form signed and dated. Date of consent ___/___/____.	___	___	___
Authorization for use and disclosure of protected health information signed and dated. <b>Non-USA institution only</b> ( <i>check NA</i> ) vs. Date of authorization ___/___/____.	___	___	___
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.	___	___	___
Treatment cannot begin prior to registration and must begin ≤30 days after randomization.	___	___	___
Pretreatment tests/procedures (see Section 4.0) must be completed within the guidelines specified in the test schedule.	___	___	___
All required baseline symptoms (see Section 10.3) must be documented and graded.	___	___	___
Study drug availability checked.	___	___	___

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Registration Check (*continued*)

Yes No NA

Blood draw kit and saliva collection kit availability checked. If not applicable ( <i>check NA</i> )	___	___	___
Patient questionnaire booklet availability checked; copies are not acceptable for this submission.	___	___	

**All responses in above section must be “Yes” unless specified as “NA.”**

<p><b>Is patient receiving active treatment?</b>                  ___ Yes. If yes, go to Stratification factors.                  ___ No. If no, continue with Registration questions.</p>	
<p>At the time of registration/randomization, the following will also be recorded:</p> <ul style="list-style-type: none"> <li>• Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat cancer.</li> </ul>	___ ___
<ul style="list-style-type: none"> <li>• Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).</li> </ul>	___ ___
<ul style="list-style-type: none"> <li>• Patient has given NCCTG permission to give blood sample(s) to outside researchers.</li> </ul>	___ ___
<ul style="list-style-type: none"> <li>• Patient has given permission to keep saliva sample(s) for use in future research to learn about, prevent, or treat cancer.</li> </ul>	___ ___
<ul style="list-style-type: none"> <li>• Patient has given permission to keep saliva sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).</li> </ul>	___ ___
<ul style="list-style-type: none"> <li>• Patient has given NCCTG permission to give saliva sample(s) to outside researchers.</li> </ul>	___ ___

**All responses in above section may be “Yes” or “No”.**

Stratification Factors

Baseline fatigue score  
 \_\_\_ 4-7  
 \_\_\_ 8-10

Duration of all prior cancer treatment in patients lifetime  
 \_\_\_ None  
 \_\_\_ ≤180 days  
 \_\_\_ >180 days

Disease status of current cancer  
 \_\_\_ Initial diagnosis  
 \_\_\_ Recurrent disease

Current tumor type  
 \_\_\_ Hematologic  
 \_\_\_ Solid tumor malignancy

Note: Patients with both types of malignancies, select hematologic.

Current treatment (chemotherapy, radiation, immunotherapy):  
 \_\_\_ Yes  
 \_\_\_ No

Assigned Treatment

\_\_\_ Panax quinquefolius (Wisconsin ginseng) vs. Placebo

Person registering \_\_\_\_\_ Signature      Registration Office specialist \_\_\_\_\_ initials

Physician \_\_\_\_\_ Signature      M - D - Y