

NCCTG N07C2: The Use of Wisconsin Ginseng (*Panax quinquefolius*) to Improve Cancer-Related Fatigue: A Randomized, Double-Blind, Placebo-Controlled Phase III Study

Fast Facts

Eligibility Criteria

1. ≥ 18 years of age.
2. 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 (0 - 10) (Linear Analogue Scale Fatigue Question 1; Appendix II).
3. The presence of fatigue ≥ 1 month prior to randomization.
4. ECOG performance score 0, 1, 2
5. 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.
Note: 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.
6. Laboratory values obtained prior to randomization
 - Hgb ≥ 11 (must be obtained ≤ 30 days; patients must not be transfused ≤ 30 days to meet this criterion)
 - Creatinine $\leq 1.2 \times$ UNL (must be obtained ≤ 180 days prior to randomization)
 - AST (SGOT) or ALT (SGPT) $\leq 1.5 \times$ UNL (must be obtained ≤ 180 days prior to randomization)
7. Negative pregnancy test done ≤ 7 days prior to registration, for women of childbearing potential only.
8. Ability to complete patient questionnaires alone or with assistance.
9. Controlled:
 - Pain (≤ 4 on Linear Analogue Scale Question 3 - Appendix II)
 - Insomnia (≤ 4 on Linear Analogue Scale Question 2 - Appendix II)
10. Willingness to provide blood/saliva samples for correlative studies.
Note: 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.

Patient Ineligibility

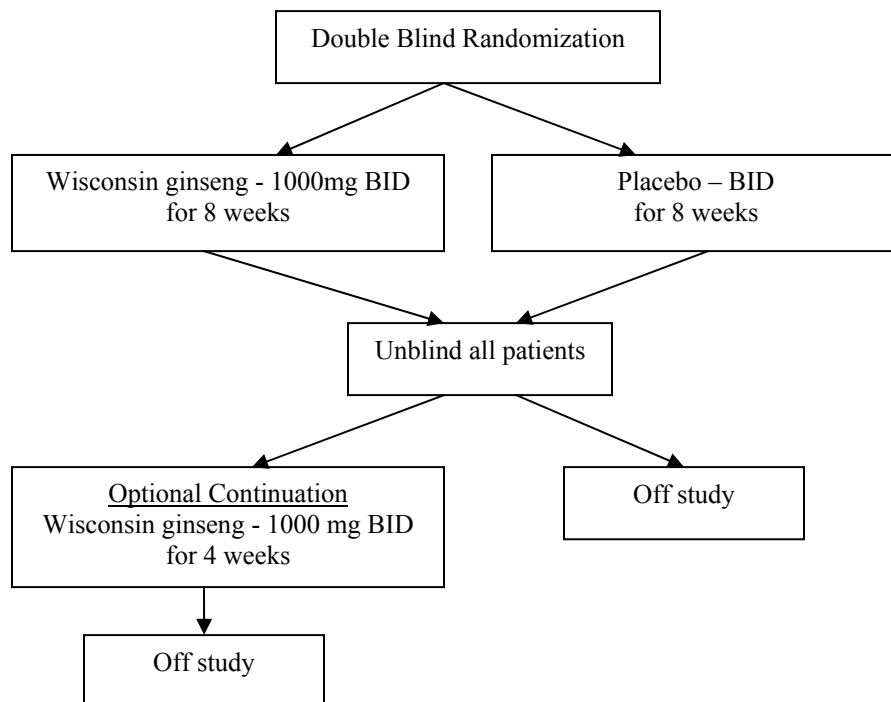
11. Hypersensitivity to ginseng.
12. Prior use of ginseng capsules for fatigue.
Note: Prior use of teas or drinks containing ginseng is allowed, however, patients will be asked to avoid these beverages while on the study.
13. Uncontrolled hypertension on more than one occasion (diastolic blood pressure > 100 , systolic > 160) measured ≤ 90 days prior to randomization.
14. Currently using any other pharmacologic agents or nonpharmacologic interventions to specifically treat fatigue including psychostimulants, antidepressants, acupuncture, etc.
Note: 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
15. Known brain metastasis or primary CNS malignancy.
16. 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).
17. Diabetes Type I or II (defined by being on oral hypoglycemics or insulin).
18. Psychiatric disorder such as severe depression, manic depressive disorder, obsessive compulsive disorder or schizophrenia. (Defined per medical history).
19. ≤ 4 weeks from major surgery to randomization, including any procedure that requires general anesthetic.
20. Any of the following:
 - Pregnant women

- Nursing women
 - Women of childbearing potential who are unwilling to employ adequate contraception
21. Pain requiring opioid pain medication, however, over the counter analgesics such as Tylenol or ibuprofen are allowed.
 22. Use of full dose of anticoagulant therapy (Exception: 1 mg/day of Coumadin for preventing catheter clots is allowed).
 23. Use of MAO inhibitors.
 24. 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.
Note: If not currently getting treatment, no chemotherapy agents ≤ 21 days prior to randomization.
 25. Malnutrition, active infection, significant pulmonary disease and cardiovascular disease as determined by the physician, as they could impact fatigue.
 26. 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").
 27. Uncontrolled nausea or vomiting or any symptom that would prevent the ability to comply with daily oral ginseng/placebo treatment.
 28. Uncontrolled thyroid disorder.
 29. Currently receiving single agent on blinded placebo controlled treatment trials.

Pre-Study Parameters

1. History and physical including weight and performance status within 30 days of registration
2. Hgb (must be obtained ≤ 30 days; patients must not be transfused ≤ 30 days to meet this criterion)
3. Creatinine, SGOT within 30 days of registration for those receiving treatment, 180 days for those who have completed treatment
4. Thyroid and/or adrenal function if clinically indicated
5. Pregnancy test within 7 days for women of childbearing potential

Treatment



-Questionnaire booklets to be filled out during study phase and optional continuation phase.