

RC08C6: White Wine for Appetite Loss: A Randomized, Controlled Non-blinded Trial

Fast Facts

Inclusion Criteria

1. ≥ 21 years of age.
2. Incurable, invasive malignancy.
3. Able to reliably take the study intervention as prescribed in this protocol.
4. No prior or current history of alcoholism.
5. Alert and mentally competent.
6. Physician estimates that patient has lost ≥ 5 pounds (2.3 kg) in weight ≤ 2 months (excluding peri-operative weight loss; documented weight loss not required) and/or have estimated caloric intake of < 20 cal/kg daily (no further documentation necessary other than an affirmative answer to this statement)
7. Patient perceives loss of appetite and/or weight as a problem. NOTE: Documentation not necessary.
8. Concurrent chemotherapy and/or radiotherapy are permitted.
9. Negative pregnancy test done ≤ 7 days prior to registration, for women of childbearing potential only.
10. Willing to abstain completely from alcohol for 4 weeks, except as prescribed in this trial. NOTE: Patients assigned to the non-wine nutritional supplement (Arm B) must be willing to abstain from wine and other alcoholic beverages for 3-4 weeks. Patients assigned to the white wine (Arm A) are allowed to take a nutritional supplement, such as Ensure or Boost if they choose to.
11. Ability to complete questionnaire(s) by themselves or with assistance.
12. Willingness to return to MCCRC enrolling institution for follow-up.

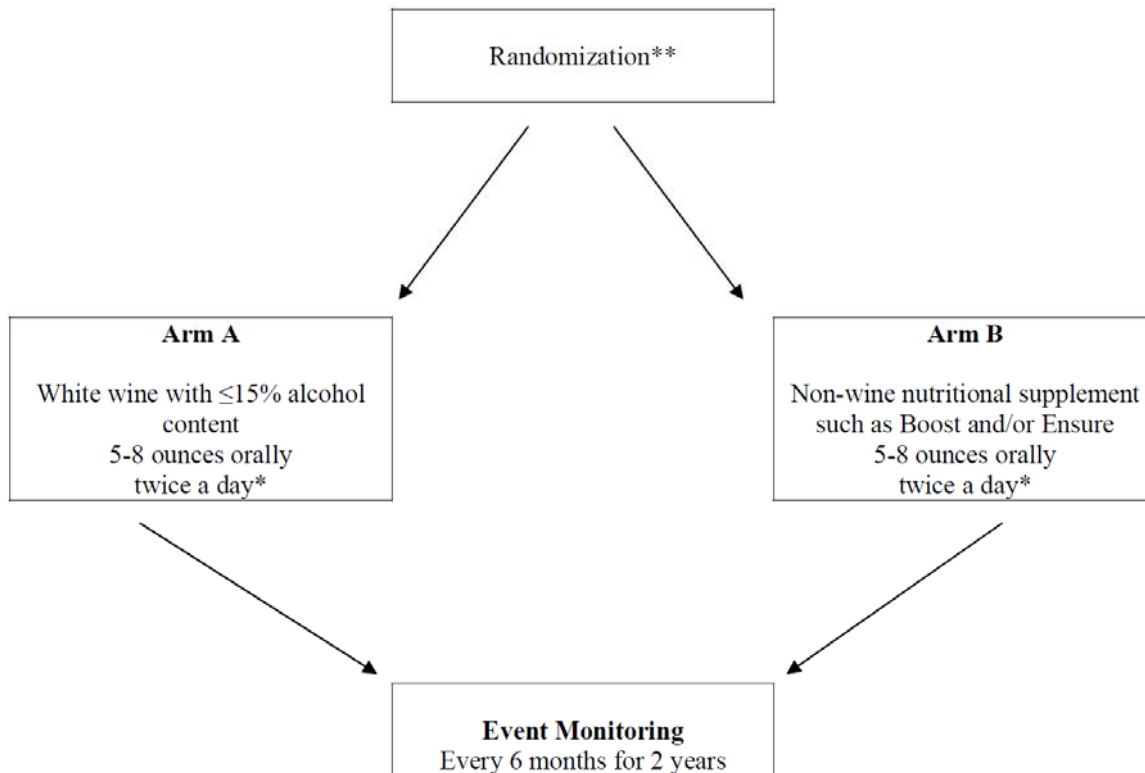
Exclusion Criteria

1. Receiving tube feedings or parenteral nutrition.
2. Current (≤ 1 month) or planned treatment with adrenal corticosteroids (short-term use of dexamethasone around days of chemotherapy is allowed for protection against emesis), androgens or progestational agents. EXCEPTION: Inhalant, topical, or optical steroid use is permissible.
3. Progestational agent (such as megestrol acetate) planned to be initiated over the next 30 days. NOTE: Patients who have been on megestrol acetate for > 1 month and are still on it and otherwise meet the eligibility criteria are permitted to enroll on this protocol and remain on megestrol acetate.
4. Known mechanical obstruction of the alimentary tract, malabsorption, or intractable vomiting (> 5 episodes/week).
5. Symptomatic or untreated brain metastases.
6. Any of the following as this regimen may be harmful to a developing fetus or nursing child:
 - Pregnant women
 - Nursing women
 - Men or women of childbearing potential who are unwilling to employ adequate contraception.

Pre-Study Parameters

1. History and physical exam, PS, AE assessment
2. Height and weight
3. Pregnancy test for women of child bearing potential (research funded)

Schema



Cycle = 21-28 days

Study intervention will be continued for a total of 3-4 weeks (sites are allowed flexibility based on when their scheduled return occurs).

* Patients randomized to Arm A may take nutritional supplements such as Boost and/or Ensure, but patients randomized to Arm B may not take wine or other alcoholic beverages.

\$200 provided to patient to buy white wine or \$100 to buy Boost and/or Ensure.