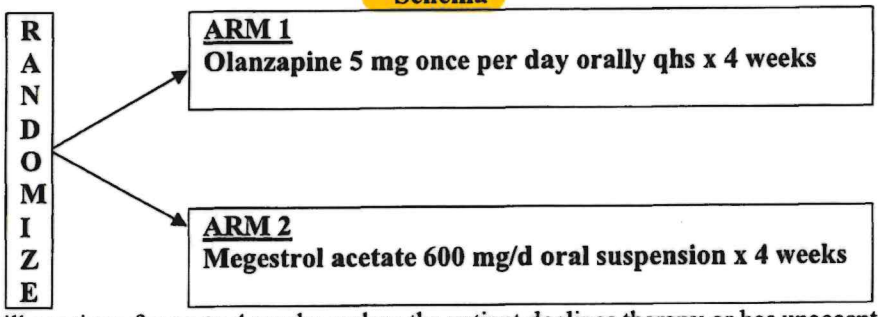
A RANDOMIZED PHASE III TRIAL OF OLANZAPINE VERSUS MEGESTROL ACETATE FOR CANCER-ASSOCIATED ANOREXIA

Eligibility Criteria (see Section 3.0)

- Diagnosis of advanced cancer. (See §3.2.1)
- Patient-reported 2-month weight loss of at least 5 pounds (2.3 kilograms) and/or physician-estimated caloric intake of less than 20 calories/kilogram of body weight per day. (See §3.2.2)
- Appetite score of 4 or worse on the "Please rate your appetite…."question (See §3.2.3)
- Not receiving ongoing tube feedings or parenteral nutrition. (See §3.2.4)
- Not currently using adrenal steroids. (See §3.2.5)
- No use of androgens, progesterone analogs, or other appetite stimulants. (See§3.2.6)
- Patient should not have poorly controlled hypertension or congestive heart failure at registration. (See §3.2.7)
- No obstruction of the alimentary canal, malabsorption, or intractable vomiting. (See §3.2.8)
- Not currently using olanzapine for another medical condition or had previously used olanzapine for chronic nausea or for any pre-existing psychotic disorder. (See §3.2.9)
- No impaired decision making capacity. (See §3.2.10).
- No presence of a hormone-sensitive tumor. (See §3.2.11).
- No previous blood clot. (See §3.2.12)
- No history of poorly controlled diabetes. (See §3.2.13).
- No LMD or known brain metastases. (See §3.2.14)
- No history of hypersensitivity to olanzapine or megestrol acetate. (See §3.2.15)
- No COVID-19 infection in the past that, in the opinion of the treating physician, had left patients with compromised taste. (See §3.2.16)
- Not pregnant and not nursing. (See §3.2.17)
- Age ≥ 18 years. (See §3.2.18)
- ECOG Performance Status 0, 1 or 2. (See §3.2.19)
- Life expectancy of 3 months or longer. (See §3.2.20)
- No treatment with another antipsychotic agent. (See §3.2.22)
- Participants must be able to speak and read English or Spanish. (See §3.2.23)

Required Initial Laboratory Values
Creatinine: ≤2.0 mg/dL
AST or ALT: ≤3 x upper limit of normal (ULN)
Glucose: ≤140 mg/dL
Granulocytes: ≥ 1000/ mm^3

Schema



Treatment will continue for up to 4 weeks, unless the patient declines therapy or has unacceptable adverse events.

Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.

Because supplies of study drug are limited, site participation in this study will be restricted (See Section 4.2.2).

If the Group credited for enrollment is a non-Alliance Group, then other requirements from the credited Group may apply.