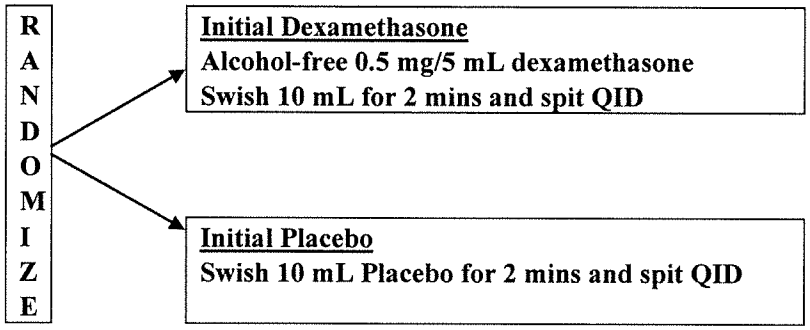
PHASE III PLACEBO-CONTROLLED TRIAL TO EVALUATE DEXAMETHASONE USE FOR EVEROLIMUS-INDUCED ORAL STOMATITIS: PREVENTION VERSUS EARLY TREATMENT APPROACHES

Eligibility Criteria (see Section 3.0)

- Current cancer diagnosis, about to receive everolimus See 3.2.1
- Not currently receiving chemotherapy See 3.2.2
- Not currently suffering from stomatitis/mucositis or mouth ulcers See 3.2.3
- Patients should not receive any other agent considered treatment for stomatitis. See 3.2.4
- No history of candida infection (thrush) within the last 3 months See 3.2.5
- Not currently being treated with corticosteroids See 3.2.6
- No uncontrolled diabetes mellitus defined by hemoglobin A1C greater than 8% See 3.2.7
- Patients must be able to read and comprehend English See 3.2 8
- Not pregnant and not nursing See 3.2.9
- ECOG Performance Status ≤ 2
- Age ≥ 18 years.

Required Initial Laboratory Values
None

Schema



Duration of treatment is 8 weeks from start of protocol treatment.

A dexamethasone prescription will be provided to all participants when they enroll to the trial. If mouth pain related to stomatitis develops at any time during the 8 week study period, patients may fill the prescription for dexamethasone oral solution from their local pharmacy. Patients will not be unblinded at this time and will continue with all study procedures (such as questionnaires, phone calls and physical exams). They will be instructed to stop taking the initially provided study medication if they start taking the prescription dexamethasone.

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

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