S1316
Malignant Bowel Obstruction Study
Information Sheet for Institutional Review Boards

- The gold standard for testing cancer therapies continues to be the randomized prospective clinical trial. This standard has been pursued admirably with regard to therapeutic cancer trials, which focus on cure; it is urgently needed in the palliative care of patients with advanced cancer and terminal disease. Palliative care focuses on patient comfort and quality of life. [1]
- There continues to be a paucity of well-designed prospective clinical trials examining state-of-the-art palliative care practices. [1]
- The absence of an established evidence base in many areas of palliative care for cancer patients is at least in part due to major challenges investigators face in designing palliative care trials.[1]
- In the absence of a firm evidence-based foundation for clinical practice, care for patients with incurable cancer is frequently based on anecdotal evidence and provider experience. Some treatment opportunities may be delayed or never considered at all, and other non-beneficial and burdensome interventions may be instituted. [1]
- SWOG 1316 is designed to provide an evidence-based foundation for the treatment and future care of cancer patients with MBO (malignant bowel obstruction).
- Although MBO is a relatively common disease encountered in clinical practice, there are no simple treatment guidelines or algorithms to follow. [1]
- Patients who elect to participate in S1316 will have the choice of being randomized to one of two standard MBO treatments or, if they prefer not to be assigned randomly, of choosing for themselves between those two standard treatments (surgery or non-surgical management).
- Treatment does not differ based on whether or not a patient was randomized: patients randomized to surgery will receive the same treatment as those who chose surgery; patients randomized to non-surgical management will receive the same treatment as those who chose non-surgical management.
- Participation in clinical research at the end of life may enable patients to find some meaning in their situation, through advancement of knowledge and potential improvements in care for others.[3]
- Patients with incurable cancer are extremely vulnerable. The challenge of obtaining informed consent can be problematic. Involved, well-meaning families or clinicians can sometimes cloud the consent process, thereby superseding the patient's wishes with their own.[2] In order to help address these concerns, the study team has had members of the SWOG Patient Advocates Committee review patient materials.
- Caregivers, family members and/or providers will be included in the consent process as the patient wishes.
- SWOG provided face-to-face training for the study site staff and investigators in how to best present the study to eligible patients. Patient advocates also participated in the training.

References:

1.Krouse, R, The International Conference on Malignant Bowel Obstruction: A Meeting of the Minds to Advance Palliative Care Research; J Pain Symptom Management, Jul 2007, 34 (1 Suppl): S1 – S6. MBCID: PMC2834265

2. Helyer, L, Surgical Approaches to Malignant Bowel Obstruction, The J of Supportive Oncology, Vol 6, #3, March 2008

3. Abernathy, A, Enhancing Enrollment in Palliative Care Trials: Key Insights from a Randomized, Placebo-Controlled Study, Vol 8, #3, May/June 2010

These are the steps the study team has taken to provide face-to-face training and training tools for investigators and staff:

- Developed examples of patients who are candidates for major intra-abdominal procedures which will be provided to study sites
- A training session for investigators and staff was held on October 24, 2014.
- Training of The Arizona Diet, Behavior, and Quality of Life Assessment Lab staff is being done by Dr. Maria Bishop, a medical oncologist and Chair of the Ethics Committee at Southern Arizona Veterans Administration Health Care System. This training will be repeated as necessary. Their agenda is available upon request.
- Designed a patient brochure for sites to use to assure consistent information in lay terms is available to potential study participants.
- Provided the protocol, study information, training and recruitment materials at the secure SWOG website for study site staff and investigators to access.

Plans for on-going study monitoring include:

- Calls will be scheduled weekly with study leadership for study site staff and clinicians during the first year of the study to address questions and concerns and to discuss progress of the study.
- Weekly accrual reports will be available for study leadership.
- An email list of key S1316 study personnel will be available to study site staff so questions and problems can be addressed outside of the weekly conference calls.