

S1316- MBO STUDY

March 4, 2016

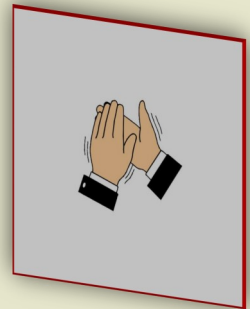
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Welcome to the 3rd edition of our monthly newsletter. Our research team has created this newsletter to provide you with the latest news about this study. If you would like to contribute to the newsletter send your comments or questions to Octavio Bojorquez at objorqu@email.arizona.edu.

One Year Anniversary

This month we are celebrating the one year anniversary of our study! We would like to thank everyone that has been involved for all their hard work to make this study possible. It is very important to address the needs of patients with advanced cancer and the challenges they face, including quality of life. Malignant bowel obstruction is a common problem for advanced cancer patients. Research addressing the needs of patients with incurable cancers is severely deficient; effectiveness has rarely been displayed by prospective trials.



Study Accrual through February 29, 2016



Accrual by Site		
Site Name	N	%
TOTAL ACCRUAL	19	100
City of Hope Comprehensive Cancer Center	1	5
Duke University Medical Center	4	21
Medical University of South Carolina	3	16
The University of Arizona Medical Center-University Campus	5	26
University of Arkansas for Medical Sciences	2	11
University of Michigan Comprehensive Cancer Center	4	21

Welcome New Sites

We would like to welcome the latest sites to join our study:

- Rush University Medical Center
- Rhode Island Cancer Center
- University of Kentucky
- University of Massachusetts
- Medical College of Wisconsin





Revision # 5 Now Available on CTSU For All Approved Sites

Major Changes Include:

- Clarified that scans for radiographic confirmation of MBO may have been done before or after admission and that scans from prior admissions must have been completed within 14 days prior to registration (see Section 5.2b in protocol).
- Clarified that patients are to remain on study follow-up even if they elect to receive follow-up care at a different institution (see Section 7.8 in protocol).
- Instructions for after-hours registration of non-randomized patients has been added to Section 13.5. This has been set-up to allow sites to register patients without accessing OPEN when research staff may not be available to perform registration OPEN. The S1316 Registration of Non-Randomized Patients during Holidays and Week-ends form is available on the SWOG and CTSU Websites.

Protocol Cards

Laminated Protocol Cards are now available. Nurses/CRAs are encouraged to add their contact information on page 2 of the card and to distribute them to any specialty that may see an MBO patient. If you need more protocol cards, contact Octavio Bojorquez at (520)626-0356 or objorqu@email.arizona.edu.

Tracking Log

Our study team has created a S1316 Patient Accrual Tracking Log to keep track of all potential patients. The log is available at the SWOG study webpage or you can request one from Octavio Bojorquez.

Investigator								
Participant Site								
Row	Patient initials (redact for submission to S1316 team)	Confirmed MBO patient? (Y/N)	When was patient admitted? (regular hours, after weekend, holiday)	Was patient every considered for study participation? (if not, list reason why not considered)	Was the patient ever approached for study participation? (If not, list reason why not approached)	Was the patient eligible for study participation? (If not, list the reason why not eligible)	Was the patient willing to participate (if not, list reason why not willing)	Was the patient registered? (if not, list reason why not registered)

Somatostatin Analogue

All patients registered to non-surgical management (Arms 2 and 4) must receive a somatostatin analogue. See protocol Section 7.3.

- Report somatostatin analogue use on the S1316 MBO Treatment form, under the Non-Surgical Treatment Section
- Report any somatostatin analogue use for surgical patients, if applicable
- See Section 7.0 of the protocol for the treatment plan

Study Tips

Submit the S1316 Off Protocol Notice within 3 days of removing a patient from active follow-up, including patients who have died.



CONFERENCES

Coordinators Call

We have a monthly (30-60 minute) teleconference for coordinators from open and planning-to-open study sites to discuss study issues with the research team. During our February call, 16 site staff joined the discussion. Our March call will be on Wednesday, March 9th, 1:00 P.M. ET, 12:00 P.M. CT, and 10:00 A.M. PT. The number to call is 1-855-295-4424. Conference code is 6221480#.



Spring 2016 SWOG Meeting

The next SWOG meeting will take place on April 27-30, 2016 at the Hyatt Regency San Francisco in San Francisco, California.

Join us at the SWOG Meeting In April!

Come and meet staff from all participating sites at an informal one hour meeting at the SWOG Meeting in San Francisco, Friday, April 29, 8:00 – 9:00 A.M. PT, at the Hyatt Regency San Francisco. This will be a great opportunity to get updates from the study leadership and exchange ideas with other participating staff. Look for more information about this meeting in future newsletters. For more information about the group meeting visit

<https://swog.org/Visitors/GpMeeting.asp>.



STUDY INFORMATION

Study information is available at swog.org and CTSU at <https://www.ctsu.org>. Have suggestions for our newsletter? Send your comments or suggestions to Octavio at oboJORQU@email.arizona.edu.

Have a question for the PI Dr. Robert S. Krouse? Feel free to call his cell phone at (520) 631-5642.