



S1316 SCHEMA

Intra-abdominal primary cancer with clinical evidence of bowel obstruction

Consent to RANDOMIZATION?

YES

NO

REGISTRATION (n=50)

Consent to Non-Randomized Treatment

REGISTRATION (n=130)

Randomization (1:1)

Treatment decision per
treating physician and patient

Arm 1
Surgery

Arm 2
Non-surgical
management

Arm 3
Surgery

Arm 4
Non-surgical
management

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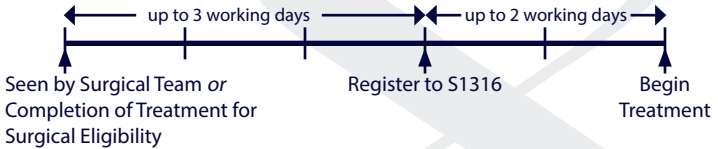
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TIMELINE FOR INITIAL PATIENT CARE



ELIGIBILITY • Patient must have:

- Clinical evidence of a small bowel obstruction below the ligament of Treitz.
- Malignant bowel obstruction (MBO) due to intra-abdominal primary cancer with incurable disease.
- Ability to tolerate major surgery.
- Radiographic confirmation of MBO ≤ 14 days prior to admission
- ≥ 18 yrs old.
- Zubrod PS 0-2 within 7 days prior to hospitalization.
- Ability to complete study questionnaires in English or Spanish.
- Primary tumor may still be in place (as long as it is not a primary large bowel obstruction from colorectal cancer).
- Patient may have received up to 2 days of anti-secretory therapy prior to randomization and still remain eligible.

INELIGIBILITY • Patient must not have:

- Signs of "acute" abdomen requiring emergency surgery.

TREATMENT:

- Surgeon must have equipoise to register patient, even if patient chooses not to be randomized.
- If patient is not randomized, they can still be followed on non-randomized arm.
- Post-registration treatment is based on best clinical judgment of treating physician. Patient whose clinical condition changes may cross over.
- It is optional *but recommended* that non-surgical patients receive a somatostatin analogue as an anti-secretory agent.

THIS CARD IS FOR SCREENING ONLY; SEE PROTOCOL FOR FULL DETAILS