TrACER Study (S1415CD)
Trial Assessing CSF prescribing Effectiveness and Risk

PURPOSE: This is supplemental information for research staff and providers to support and clarify information about patient participation in the TrACER study in congruence with the approved protocol and consent. See the S1415CD protocol at http://swog.org/.

This is not intended for patient distribution. Materials presented to patients require IRB approval.

Study Overview for Investigators

ABOUT THE STUDY

- Although evidence-based clinical practice guidelines for prescribing primary prophylactic colony stimulating factors (PP-CSF) have been available for nearly two decades, multiple studies show that the gap between best scientific evidence and clinical practice is wide for PP-CSF prescribing. Between 55% and 95% of PP-CSFs prescribing is inconsistent with evidence-based national guidelines.
- Lack of adherence to guidelines has significant financial implications for patients and the health care system. Both overuse and underuse of PP-CSF expose patients to unnecessary risks.
- This pragmatic trial is designed to test an intervention to increase compliance with guidelines and lower rates of febrile neutropenia (FN) while also generating high quality evidence to assess effectiveness of PP-CSF on reducing rates of FN for patients receiving intermediate-risk chemotherapy regimens. Outcomes to be assessed include rates of FN, adherence to clinical practice guidelines, FN-related ED visits and hospitalizations, health-related quality of life, and short-term mortality.
- For more information on the study background, objectives and eligibility, please reference the study protocol sections 1.0, 2.0 and 5.0.

STUDY DESIGN

Each component has been assigned to one of the four study groups: Group 1 (Cohort); Group 2 (Randomized to Usual Care); Group 3 (Randomized to Intervention); Group 4 (Randomized to Intervention). See Component Schema in the S1415CD Protocol for a description of each group.

- The study intervention and randomization are at the NCORP component level, not the patient level.
- All intervention arm components (Groups 3 and 4) will be required to modify their existing order systems to include standing orders for CSF for high-risk regimens and exclude orders for CSF for low-risk regimens. Group 3 will also include standing orders for CSF for intermediate-risk regimens. Group 4 will exclude orders for CSF for intermediate-risk regimens.
- At intervention arm components, guideline-informed standing orders to include/exclude CSF will be added to the existing EHR, but the physician always has the option to override. Overriding orders is not a protocol deviation.
- This study does not recommend a specific drug or dose to be prescribed. The prescribing of a specific CSF is at the doctor's discretion based on the patient's treatment plan.

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PATIENT PARTICIPATION

- Patients scheduled to receive regimens of all risk levels (high, intermediate and low) should be registered to the trial. In the informed consent, the phrase "moderate risk" was used to describe patients at intermediate risk for febrile neutropenia to enhance readability among patients. Intermediate risk is the correct clinical term used in the NCCN guidelines.
- Patient participation in this study only involves consenting to data collection. Patients will be asked to complete questionnaires at three different time points in their treatment about their experiences with CSFs and allow researchers access to their medical records.
- Patients may participate regardless of whether they are prescribed CSF. The study is interested in collecting data from patients who do and do not receive CSF.
- Patients are allowed to participate in other clinical trials while participating in TrACER. However, patients must not be participating in or plan to participate in other clinical trials that involve investigational systemic cancer treatments or investigational uses of CSF while on this study. See protocol Section 5.0 for eligibility criteria. For questions, please contact CancerControlQuestion@crab.org, or call 206-652-2267.