

KGF Study Roundtable
2013 BMT Tandem meeting
February 12, 2013

Study Overview

- KGF: Kepivance, palifermin; used for decreasing oral mucositis in HSCT patients.
- KGF Study: SC06-02: #20050187: A prospective cohort study comparing outcomes of patients receiving HCT for hematologic malignancies with and without Kepivance.
- Study design: Matched pair comparison between the exposed and unexposed cohorts. Patients are matched on certain protocol defined variables.
- Accrual goal: 2400 cases (exposed) and 2400 controls (unexposed).

Update on progress of the study

- Accrual update: Matching eligible cases to eligible controls occurs three times a year. If a match is found, both patients (case and control) are accrued to the study.
 - a. Current accrual: 2094 matched pairs
- Accrual goal: 2400 matched pairs
- Next match: March, 2013
- Data collection
 - a. Regular follow up
 - i. cRF forms
 - ii. Form 2504: study follow up
 - iii. Form 2503: pre-FN2 data collection
 - b. Pathology reports—confirmation of a reported new malignancy
 - c. Data discrepancy resolution
 - d. Changes to study population

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What kind of CIBMTR correspondence/requests should centers expect to see for this study?

- Monthly study specific forms due lists
- Pathology report requests
- Confirmation of data discrepancies (different answers reported on different forms)
 - i. Discrepancies may or may not stop the processes of the report form
- Confirmation of the patients consent status