



A Randomized, Double-blind, Phase III Study Evaluating Fixed Dose, Once-Per-Cycle Pegylated Filgrastim (SD/01) vs Daily Filgrastim to Support Chemotherapy for Breast Cancer

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Background:

- It has been shown prolonged neutropenia associated with chemotherapy administration can be significantly decreased by daily Filgrastim. Pegylated Filgrastim is a sustained duration form administered once per chemotherapy cycle. This study was performed to compare the administration of daily Filgrastim vs. once per cycle Pegylated Filgrastim

Materials and Methods:

- Double-blind randomized study of high risk breast cancer patients, stage II-IV.
- Chemotherapy consisted of 4 cycles of Doxorubicin and Docetaxel
- 157 patients were randomized to receive Pegylated Filgrastim at a single fixed dose of 6 mg on day 1 of each cycle of chemotherapy vs. daily Filgrastim.
- Those patients on the Pegylated Filgrastin arm received a placebo injection on all other days of the chemotherapy cycle.
- Baseline demographics were equally matched between the two groups

Results:

- The duration of severe neutropenia in cycle 1 was not significantly different at 1.6 vs 1.8 days.
- There was no difference in the mean duration of neutropenia with any of the chemotherapy cycles between the two groups
- The fixed dose of Pegylated Filgrastim was adequate for all weights of patients in this study
- Chemotherapy compliance was > 90% for both groups
- Cytokine related bone pain was not significantly different at 42% (Filgrastim) vs 37% (Pegylated Filgrastim)
- Overall, adverse events were not significantly different.

Authors' Conclusions

- A 6 mg dose of Pegylated Filgrastim on day 1 of each chemotherapy cycle is as effective as daily Filgrastin
- Pegylated Filgrastim and daily Filgrastim are equally tolerated
- Weight of the patients did not effect the efficacy or toxicity of Pegylated Filgrastim
- This fixed dose of Pegylated Filgrastim may increase compliance and efficacy of treatment

Clinical/Scientific Implications:

- This study shows a fixed dose of Pegylated Filgrastin administered on the first day of each chemotherapy cycle is just as effective as daily dosing, without a change in the toxicity profile.
- Clearly, this will benefit patients by way of convenience and higher likelihood of compliance to the prescribed treatment course. Also See [Abstract 27: A single Dose of Pegylated Filgrastim \(SD/01\) is as effective as Daily Filgrastim for Hematologic Support of Chemotherapy in Breast Cancer Patients: Results of a Randomized, Double-Blind, Phase 3 Trial](#)

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