Clinical efficacy of biosimilar filgrastim in Fernando Fonseca Hospital, Portugal

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Introduction

Given that biosimilar products are not generic products, a switch from filgrastim to a biosimilar filgrastim could be considered a change in clinical outcome. Due to the nature and variability of manufacturing processes for biopharmaceuticals, biosimilar filgrastim has the potential to result in differences between safety and efficacy when compared with its referential product. Phase III studies have demonstrated their bioequivalence in terms of clinical efficacy and safety profile. Clinical efficacy was demonstrated comparing both products regarding duration of severe neutropenia [DSN; ANC (absolute neutrophil count) < 0,5 x10^9/l]; time to ANC recovery (ANC > 3 x10^9/l); mean number of injections among other endpoints.

Objectives

Evaluate biosimilar filgrastim (Nivestin®) efficacy in Hospital Fernando Fonseca clinical setting during its first six months usage.

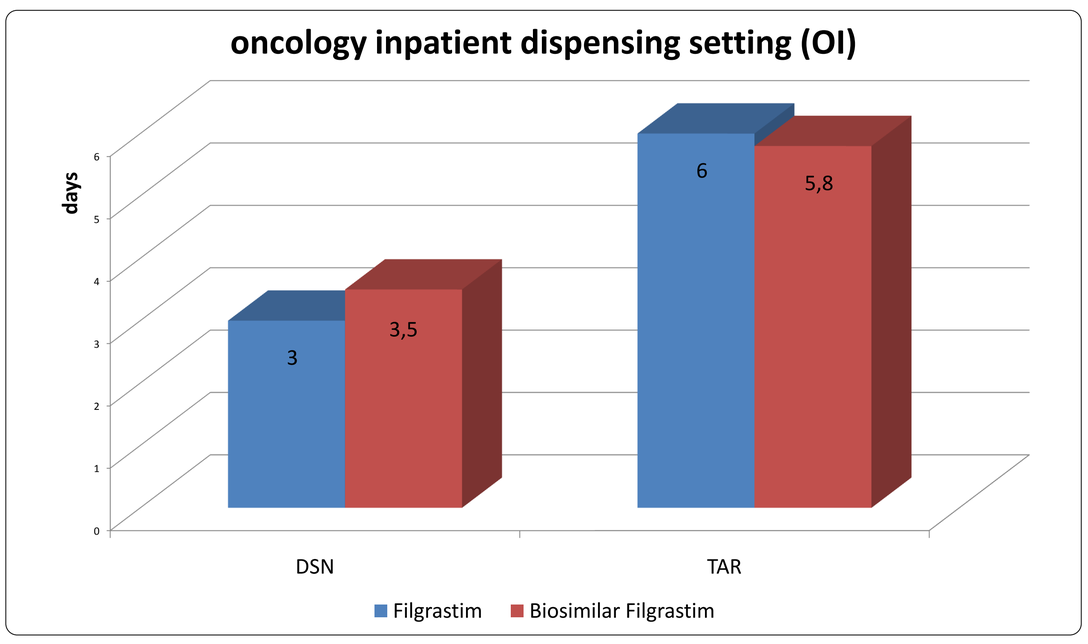
Study design

This is an observational, transversal, non-randomised, retrospective study. Two analyzing periods were created: October 2010 – March 2011 (Filgrastim data) and April 2011-September 2011 (biosimilar Filgratim data). To our entering data unit which was the product dispensing act, we called episode. Inside each period, we have identified four typologies, of different dispensing settings: non-oncology inpatient dispensing setting (NOI); oncology inpatient dispensing setting (OI); prophylactic-dispensing outpatient oncology setting (POO); treatment-dispensing outpatient oncology setting (TOO). Endpoints for each of these settings were: NOI and OI - DSN (ANC ≤ 0,5 x10^9/l) and time to ANC recovery[TAR (ANC > 3 x10^9/l)]; POO - treatments percentage and mean number of injections; TOO – Re-treatments percentage and mean number of injections (MNI).

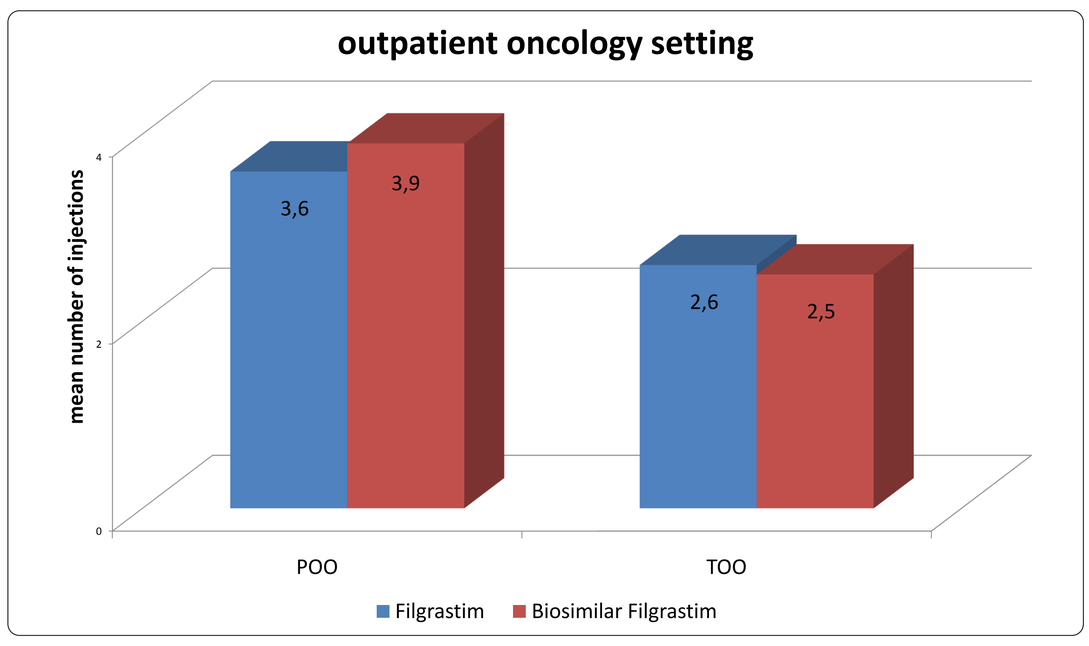
Results

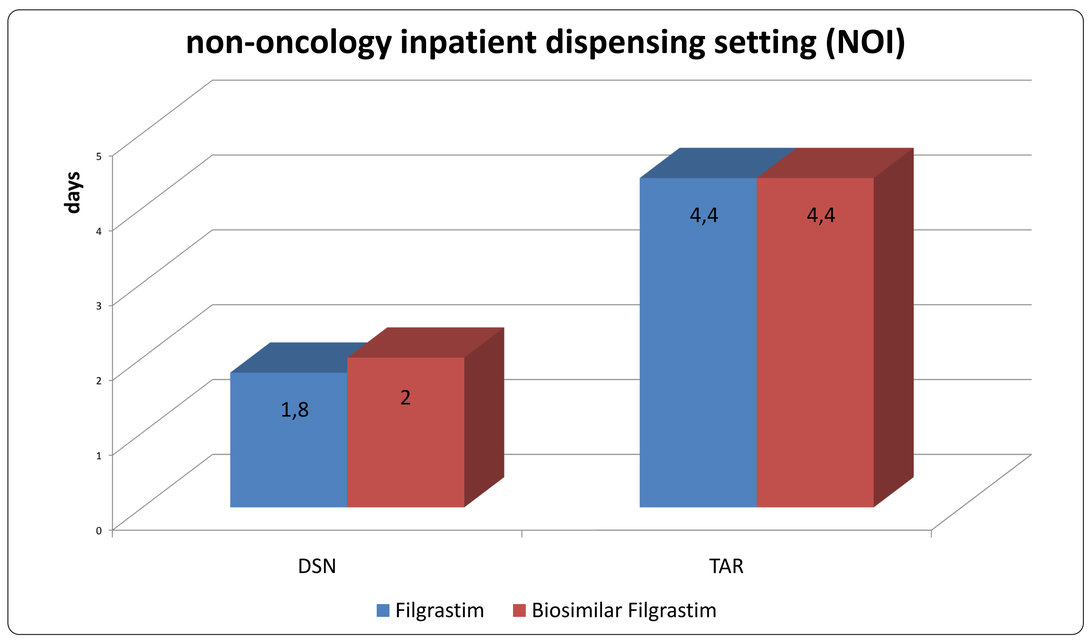
Filgrastim data. In NOI there were 8 valid episodes with mean DSN =1,8 days and mean TAR=4,4 days; in OI there were 4 episodes with mean DSN =3 days and mean TAR=6 days; in TOO there were 80 episodes with no re-treatments (0%) and MNI=2,6; in POO there were 113 episodes in which 3 were treatments (2,7 %) and MNI= 3,6.

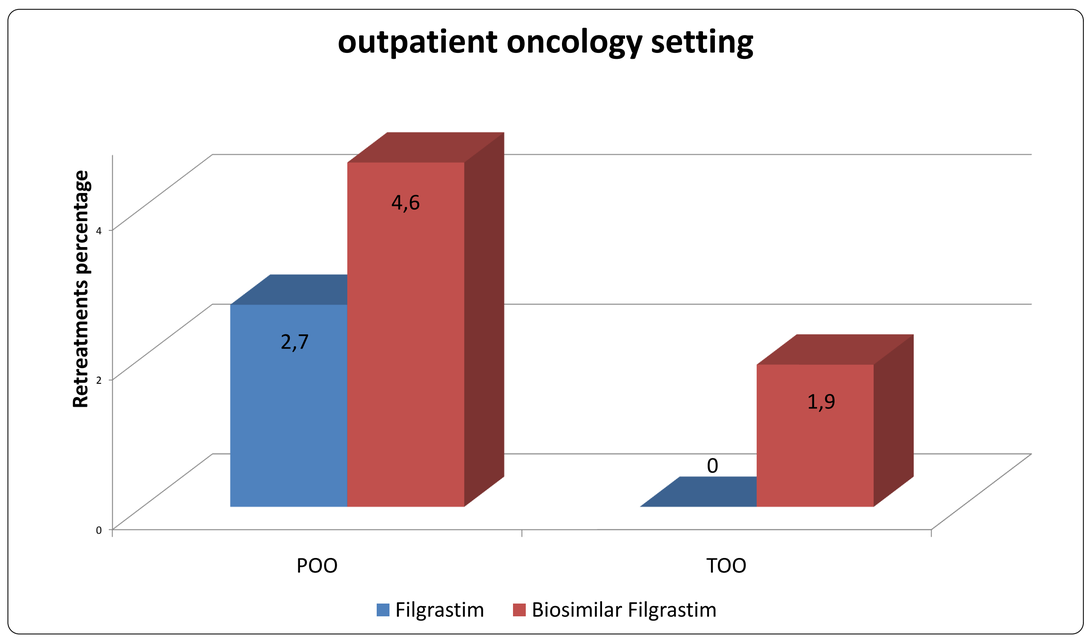
Biosimilar Filgrastim data in NOI there were 23 valid episodes which translates in mean DSN =2 days and mean TAR=4,4 days; in OI there were 9 episodes which translates in mean DSN =3,5 days and mean TAR=5,8 days; in TOO there were 53 episodes with 1 re-treatment (1,9%) and MNI=2,5; in POO there were 108 episodes in which 5 were treatments (4,6%) and MNI=3,9.



Results (cont)







Conclusions

✓According to our results there doesn't seem to exist significant differences in terms of clinical efficacy among both filgrastim. Moreover, there were no reports of any different safety profile. Given the fact that there was a tremendous reduction in hospital expenditures with biosimilar filgrastim this alternative provides a highly cost-effective option.

Bibliography

1. 2010 update of EORTC guidelines for the use of G-CSF to reduce the incidence of chemotherapy-induced febrile neutropenia in adult patients with lymphoproliferative disorders and solid tumors. Aapro MS *et al*. European Journal of Cancer 47 (2011) 8-32.

2. A phase III randomized equivalence study of biosimilar filgrastim versus Amgen Filgrastim in Patients receiving myelosuppressive chematherapy for breast cancer. Waller C. *et al*. Onkologie 2010; 33:504-511.

3. XM02, first G-CSF biosimilar, is safe and effective in reducing the duration of severe neutropenia and incidence of febrile neutropenia in patients with non-Hodgkin lymphoma receiving chemotherapy. Engert A. *et al*. Leukemia & Lymphoma, March 2009; 50(3): 374-379.

4. Incidence of febrile neutropenia and myelotoxiciy of chemotherapy: a meta-analysis of biosimilar G-CSF studies in breast cancer, lung cancer, and non-hodgkin's lymphoma. Engert A. *et al*. Onkologie 2009 Oct; 32(10): 599-604. Epub 2009 Sep 14.

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