

CADTH Reference List

Reference Filgrastim (Neupogen) for Pediatric Patients With Cancer

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Key Message

No literature was identified regarding the clinical effectiveness of reference filgrastim (Neupogen) for pediatric patients with cancer.

Research Question

What is the clinical effectiveness of reference filgrastim (Neupogen) for pediatric patients with cancer?

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, Embase, the Cochrane Library, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were filgrastim and pediatric patients. No filters were applied to limit the retrieval by study type. Conference abstracts, comments, newspaper articles, editorials, and letters were excluded. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2001 and August 16, 2021. Internet links were provided, where available.

Selection Criteria and Summary Methods

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in Table 1. Full texts of study publications were not reviewed. The Overall Summary of Findings was based on information available in the abstracts of selected publications.

Results

Additional references of potential interest that did not meet the inclusion criteria are provided in Appendix 1.

Table 1: Selection Criteria

| Criteria | Description |
|----------------------|--|
| Population | Pediatric patients with cancer including patients with acute myeloid leukemia, severe chronic neutropenia, or patients receiving myelosuppressive chemotherapy or myeloablative chemotherapy with or without bone marrow transplantation follow-up |
| Intervention | Reference filgrastim (Neupogen) |
| Comparator | No treatment; placebo; other supportive care interventions (e.g., pharmacological and/or non-pharmacological treatment options) |
| Outcomes | Clinical effectiveness (e.g., clinical response, health-related quality of life, mortality) and safety (e.g., adverse events, withdrawal due to adverse event) |
| Study designs | Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies |

Overall Summary of Findings

No relevant literature was found regarding the clinical effectiveness or safety of reference filgrastim for pediatric patients with cancer; therefore, no summary can be provided.

References

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials

No literature identified.

Non-Randomized Studies

No literature identified.

Appendix 1: References of Potential Interest

Previous CADTH Reports

1. Kumar D, Horton J. Switching from reference to biosimilar filgrastim in pediatric patients. *CADTH reference list: summary of abstracts*. Ottawa (ON): CADTH; 2021: <https://cadth.ca/sites/default/files/pdf/htis/2021/RB1575%20Nivestym%20Final.pdf>. Accessed 2021 Aug 27.

Systematic Reviews and Meta-Analyses

Mixed Population

2. Holdsworth MT, Mathew P. Efficacy of colony-stimulating factors in acute leukemia. *Ann Pharmacother*. 2001 Jan;35(1):92-108. [PubMed](#)

Randomized Controlled Trials

Mixed or Alternative Population

3. Ernst P, Bacigalupo A, Ringden O, et al. A phase 3, randomized, placebo-controlled trial of filgrastim in patients with haematological malignancies undergoing matched-related allogeneic bone marrow transplantation. *Arch Drug Inf*. 2008;1(3):89-96. [PubMed](#)
4. Carlsson G, Ahlin A, Dahllof G, Elinder G, Henter JI, Palmblad J. Efficacy and safety of two different rG-CSF preparations in the treatment of patients with severe congenital neutropenia. *Br J Haematol*. 2004 Jul;126(1):127-132. [PubMed](#)
5. Usuki K, Urabe A, Masaoka T, et al. Efficacy of granulocyte colony-stimulating factor in the treatment of acute myelogenous leukaemia: a multicentre randomized study. *Br J Haematol*. 2002 Jan;116(1):103-112. [PubMed](#)

Non-Randomized Studies

Mixed or Alternative Population

6. Tanni KA, Truong CB, Almahasis S, Qian J. Safety of marketed cancer supportive care biosimilars in the US: a disproportionality analysis using the Food and Drug Administration Adverse Event Reporting System (FAERS) database. *BioDrugs*. 2021 March;35(2):239-254. [PubMed](#)
7. Niinomi I, Hosohata K, Oyama S, Inada A, Wakabayashi T, Iwanaga K. Evaluation of adverse events associated with filgrastim originator and biosimilar using a spontaneous reporting system database. *Pharmazie*. 2020 04 06;75(4):151-153. [PubMed](#)
8. Rastogi S, Shukla S, Sharma AK, et al. Towards a comprehensive safety understanding of granulocyte-colony stimulating factor biosimilars in treating chemotherapy associated febrile neutropenia: trends from decades of data. *Toxicol Appl Pharmacol*. 2020 05 15;395:114976. [PubMed](#)
9. Buyukavci M, Yildirim ZK. The comparison of the efficacy and safety of original and biosimilar filgrastim in prevention of chemotherapy-induced neutropenia in children with cancer. *Eurasian J Med*. 2019 Jun;51(2):112-115. [PubMed](#)
10. Yousofian S, Miri-Aliabad G, Kiumarsi A, Ramim T. Effectiveness of filgrastim and polyethylene glycol-filgrastim in the treatment of postchemotherapy neutropenia in children: phase I clinical trial. *Indian J Med Paediatr Oncol*. 2019 01 Jan;40(1):101-104.
11. Mousavi S, Dadpoor M, Ashrafi F. Granulocyte colony-stimulating factor use in a large Iranian hospital: comparison with American Society of Clinical Oncology (ASCO) clinical practice guideline. *Int J Hematol Oncol Stem Cell Res*. 2016;10(2):85-91. [PubMed](#)
12. Guneyssel O, Onur OE, Denizbasi A. Effects of recombinant human granulocyte colony-stimulating factor (filgrastim) on ECG parameters in neutropenic patients: a single-centre, prospective study. *Clin Drug Investig*. 2009;29(8):551-555. [PubMed](#)
13. Yilmaz D, Ritchey AK. Severe neutropenia in children: a single institutional experience. *J Pediatr Hematol Oncol*. 2007 Aug;29(8):513-518. [PubMed](#)
14. Dale DC, Cottle TE, Fier CJ, et al. Severe chronic neutropenia: treatment and follow-up of patients in the Severe Chronic Neutropenia International Registry. *Am J Hematol*. 2003 Feb;72(2):82-93. [PubMed](#)

Randomized Controlled Trials

Mixed or Alternative Intervention

15. Alonzo TA, Kobrinsky NL, Aledo A, Lange BJ, Buxton AB, Woods WG. Impact of granulocyte colony-stimulating factor use during induction for acute myelogenous leukemia in children: a report from the Children's Cancer Group. *J Pediatr Hematol Oncol*. 2002 Nov;24(8):627-635. [PubMed](#)

Non-Randomized Studies

Mixed or Alternative Intervention

16. Lohmann DJA, Asdahl PH, Abrahamsson J, et al. Use of granulocyte colony-stimulating factor and risk of relapse in pediatric patients treated for acute myeloid leukemia according to NOPHO-AML 2004 and DB AML-01. *Pediatr Blood Cancer*. 2019 06;66(6):e27701. [PubMed](#)
17. Luczynski W, Muszynska-Roslan K, Krawczuk-Rybak M, Kuzmicz M, Iwaszkiewicz-Pawlowska A, Kaliszewski J. Results of IDA-FLAG programme in the treatment of recurrent acute myeloblastic leukaemia—preliminary report. *Med Sci Monit*. 2001 Jan-Feb;7(1):125-129. [PubMed](#)