

Darbepoetin Alfa Administered Every Two Weeks Reduces Chemotherapy-Induced Anemia to the Same Extent as Recombinant Human Erythropoietin (Epoetin Alfa), But With Less-Frequent Dosing

Authors

Barry C. Mirtsching, J. Thaddeus Beck, Veena Charu, N.T. Nazha, N. Simon Tchekmedyan, H. Ghazal, R.J. Blachly, Dianne Tomita, and Gregory Rossi

Origin of Study

USA

Type of Study

RETROSPECTIVE ANALYSIS OF CLINICAL TRIAL DATA

Objective

Evaluate the relative efficacy of darbepoetin alfa administered every 2 weeks and epoetin alfa, given 1 or 3 times a week

Study Design

Data from three multicenter trials of similar design were pooled, including interim data from one ongoing study.

Patients

All patients were receiving chemotherapy for nonmyeloid malignancies and were anemic (hemoglobin level ≤ 11.0 g/dL).

All patients received open-label study drug (darbepoetin alfa or epoetin alfa) subcutaneously:

- 287 patients in the darbepoetin alfa group received a starting dose of 3.0 $\mu\text{g}/\text{kg}$ every 2 weeks.
- 115 patients received epoetin alfa at a starting dose of either 150 U/kg 3 times a week ($n = 53$) or 40,000 U once weekly ($n = 62$).

Observations

The safety profiles of both study drugs were similar.

Efficacy endpoints are shown below:

Hematopoietic Response to Erythropoietic Therapy

HEMATOPOIETIC RESPONSE	DARBEPOETIN ALFA ($n = 287$)	EPOETIN ALFA ($n = 115$)
Kaplan-Meier proportion (95% CI)	79% (73%–85%)	71% (61%–81%)
Mean hemoglobin change (g/dL)		
After 4 weeks (95% CI)	0.4 (0.2–0.5)	0.5 (0.2–0.7)
After 12 weeks (95% CI)	1.7 (1.5–1.9)	1.3 (1.0–1.6)
Proportion requiring RBC transfusions		
Week 1 to end of treatment (95% CI)	23% (18%–28%)	23% (16%–32%)
Week 5 to end of treatment (95% CI)	15% (11%–20%)	14% (8%–22%)

Conclusions

The therapeutic impact of darbepoetin alfa (3.0 $\mu\text{g}/\text{kg}$ every 2 weeks) in treating chemotherapy-induced anemia was similar to that observed with epoetin alfa but was achieved with less-frequent dosing.

Discussion

In cancer patients receiving multiple-cycle chemotherapy, fatigue and reduced quality of life are debilitating effects of chemotherapy-induced anemia. Treatment with recombinant human erythropoietin (epoetin alfa [Epoen, Procrit]) requires frequent subcutaneous injections, usually 1 or 3 times weekly, whereas darbepoetin alfa (Aranesp), with an approximately threefold longer half-life and greater biologic activity than epoetin alfa, permits less-frequent dosing.

Darbepoetin Alfa Reduces Chemotherapy-Induced Anemia to the Same Extent as Epoetin Alfa, But With Less-Frequent Dosing

The objective of the current analysis by Mirtsching and colleagues was to evaluate the relative efficacy of darbepoetin alfa administered every 2 weeks and epoetin alfa given either once a week or 3 times a week.

Data from three multicenter trials of similar design were pooled, including interim data from one ongoing study. All studies enrolled anemic (hemoglobin level ≤ 11.0 g/dL) patients receiving chemotherapy. All patients had nonmyeloid malignancies and received either darbepoetin alfa or epoetin alfa subcutaneously. In the darbepoetin alfa group, 287 patients received a starting dose of 3.0 $\mu\text{g}/\text{kg}$ every 2 weeks. In the epoetin alfa group (115 patients), 53 patients received a starting dose of 150 U/kg 3 times weekly, and 62 patients received a starting dose of 40,000 U once weekly.

The clinical outcomes (viz, hematopoietic response, mean hemoglobin level change after both 4 and 12 weeks, and transfusion requirements) were virtually identical in both groups. Darbepoetin alfa given every 2 weeks was well tolerated, with a safety profile comparable to that of epoetin alfa.

"The properties of darbepoetin alfa, including a long half-life and a safety profile that has been demonstrated over a wide range of doses, allow for ongoing studies of its front-loading and reduced-frequency dosing strategies," said Barry Mirtsching, MD.

Key Points

- Darbepoetin alfa is clinically equivalent to epoetin alfa in treating chemotherapy-induced anemia but requires less-frequent dosing.
- At a dose of 3 $\mu\text{g}/\text{kg}$ given every 2 weeks, darbepoetin alfa safely increases the hemoglobin concentration to the same extent as epoetin alfa.
- Transfusion requirements did not differ in the retrospective comparison of darbepoetin alfa and epoetin alfa.
- With a fixed dose of darbepoetin alfa, there is no need to discard medication, and the nursing time required to administer the dose is reduced.

References

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