The Safety and Efficacy of DA-3030 (Recombinant Human Granulocyte Colony-Stimulating Factor) in Neutropenia after Induction Chemotherapy in Patients with Acute Myelogenous Leukemia

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Background We conducted a prospective, controlled study to determine the safety and efficacy of DA-3030 (Leucostim®) after induction chemotherapy in patients with acute myelogenous leukemia(AML).

Methods After induction chemotherapy with idarubicin(12 mg/m²/day for 3 days) and cytarabine(200 mg/m²/day for 7 days), 26 patients with newly diagnosed AML were assigned to receive DA-3030(200 µg/m²/day), starting on day 9, until there was neutrophil recovery or a treatment failure. To compare the outcome of DA3030, a historical control group of 16 patients were selected among 153 patients registered at Asan medical center between June 1989 and March 1996. They received daunorubicin(45 mg/m²/day for 3 days) and cytosine-arabinoside(200 mg/m²/day for 7 days) without G-CSF.

Results Complete remission(CR) rate was 72% versus 94% in controls (P = 0.18). Treatment with DA3030 was not associated with major adverse events. The most frequently reported side effects related to the study drug were musculo-skeletal pain (17%) and headache (17%). The recovery of neutrophil to more than than 1,000/µL was faster in the DA3030 group but the difference was not significant (22 vs 27 days; P = 0.159). However, among patients who achieved CR, the recovery of neutrophil to more than 1,000/µL was significantly faster in the DA3030 group (23 vs 27 days; P = 0.024). There were no differences in the incidence of febrile episode, and duration of parenteral anti-infective therapy. The median duration of hospitalization was significantly reduced 32 days in the DA3030 group than 56 days in the control group (P = 0.04).

Conclusion The DA3030 is tolerable and relatively effective for the treatment of neutropenia after induction chemotherapy in patients with AML.