

High-dose cytarabine improves outcome in patients with AML in EORTC-GIMEMA AML-12 Trial

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Results of the EORTC and GIMEMA (Gruppo Italiano Malattie Ematologiche dell' Adulto) AML-12 Trial appearing in the *Journal of Clinical Oncology* show that high-dose cytarabine in induction treatment improves outcome of adult patients with acute myeloid leukemia (AML). In particular, high-dose cytarabine produces higher remission and survival rates than the standard-dose cytarabine in patients younger than age 46 years old.

Dr. Roelof Willemze of the Leiden University Medical Centre and lead author of this report explains, "The most commonly administered induction regimen for [patients](#) with AML is a daily dose of 100 to 200 mg/m² of cytarabine for seven to ten days in combination with three days of an anthracycline. This treatment has been shown to result in complete remission rates of 60% to 80% depending on age of the patient as well as genetic and molecular characteristics of the disease. Up until now, however, we did not have clear consensus on the benefit of higher dosages of cytarabine."

The AML-12 included 1,942 newly diagnosed patients with AML aged 15 to 60 years and compared remission induction treatment with daunorubicin, etoposide, and either standard-dose (100 mg/m² per day by continuous infusion for 10 days) or high-dose (3,000 mg/m² every 12 hours by 3-hour infusion on days 1, 3, 5, and 7) cytarabine. Patients in complete remission received a single consolidation cycle containing

daunorubicin and intermediate dose cytarabine.

At a median follow-up of six years, overall survival was 38.7% for patients receiving standard-dose and 42.5% for those receiving high-dose cytarabine (log-rank test $P = 0.06$; multivariable analysis $P = 0.009$).

For patients younger than 46 years old, survival was 43.3% with standard-dose treatment and 51.9% with high-dose treatment ($P = 0.009$; multivariable analysis $P = 0.003$). Survival for patients 46 to 60 years old was 33.9% and 32.9%, respectively ($P = 0.91$).

Complete remission rates were 72.0% for standard-dose and 78.7% for high-dose (P

Provided by European Organisation for Research and Treatment of Cancer

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