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Statistical analysis for the Cytarabine (Ara-C) in Children With Acute Promyelocytic Leukemia (APL) (NCT01191541)

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Statistical analysis

The primary objective was to demonstrate the noninferiority of DNR alone compared to DNR+Ara-C in terms of the DFS rate at 2 years. Assuming a 95% rate of DFS in the two groups, a margin of -14% , 5% type 1 error, and 80% power, 31 evaluable patients per group were required to draw a noninferiority conclusion.

The characteristics of all of the included patients were summarized using cross-tabulations (for categorical variables) and quantiles (e.g., the median; for continuous variables). Nonparametric tests were used to analyse comparisons between groups (i.e., χ^2 and Fisher's exact tests for categorical variables). EFS, DFS and OS were estimated using the Kaplan -Meier method, and log-rank tests were used for comparisons. All *P* values were two-sided, and those with values of 0.05 or less were considered to be statistically significant. All statistical analyses were performed using

SPSS software.