Azacitidine as post-remission therapy in elderly patients with acute myeloid leukemia significantly prolongs disease-free survival: interim results from a prospective, randomized, open-label, Phase 3, multicenter trial

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BACKGROUND AND RATIONALE

• Approximately 136 patients will be enrolled in the trial
• Exclusion criteria include:
  1. To evaluate differences between the 5-Aza and BSC arms in:
  2. To evaluate the difference in DFS between the 5-Aza and BSC arms at 2 and 5 years post-
  3. Only about half of elderly patients with acute myeloid leukemia (AML) achieve complete

METHODS

• Between-group comparisons of DFS and OS are being carried out using a log-rank test,
• Results are presented here for DFS and OS only. The data reported are preliminary results
• The median age of patients at enrollment was 71 (interquartile range [IQR] 66–75) years

RESULTS

• Patients
  • Approximately 136 patients will be enrolled in the trial
  • Exclusion criteria include

Table 1. Baseline characteristics of patients in 5-Aza randomized to 5-Aza maintenance

- enrollment or fibrin level more than twice the ULN, except in case of AML; infection
- changes in quality of life scores from diagnosis to the second, fourth, and sixth post-

CONCLUSIONS

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REFERENCES

2. Sekeres MA. Haematologica 2008;93:1769–72
4. Conclusions

• Safety
  • At data cut-off, nine patients in the 5-Aza arm and three randomized to BSC remained in
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