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Venetoclax combined with daunorubicin and cytarabine (2 + 6) as induction treatment in adults with newly diagnosed acute myeloid leukemia: a phase 2, multicenter, single-arm trial

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Abstract

Background: Venetoclax (Ven) combined with intensive chemotherapy was proven effective in the management of acute myeloid leukemia (AML). However, the severe and prolonged myelosuppression remains a concern to worry about. To explore more appropriate combination regimens, we designed Ven combining daunorubicin and cytarabine (DA 2 + 6) regimen as induction therapy, aimed to evaluate the effectiveness and safety in adults de novo AML.

Methods: A phase 2 clinical trial was performed in 10 Chinese hospitals to investigate Ven combined with daunorubicin and cytarabine (DA 2 + 6) in patients with AML. The primary endpoints were overall response rate (ORR), comprising of complete remission (CR), complete remission with incomplete blood cell count recovery (CRi), and partial response (PR). Secondary endpoints included measurable residual disease (MRD) of bone marrow assessed by flow cytometry, overall survival (OS), event-free survival (EFS), disease-free survival (DFS), and the safety of regimens. This study is a currently ongoing trial listed on the Chinese Clinical Trial Registry as ChiCTR2200061524.

Results: Overall, 42 patients were enrolled from January 2022 to November 2022; 54.8% (23/42) were male, and the median age was 40 (range, 16-60) years. The ORR after one cycle of induction was 92.9% (95% confidence interval [CI], 91.6-94.1; 39/42) with a composite complete response rate (CR + CRi) 90.5% (95% CI, 89.3-91.6, CR 37/42, CRi 1/42). Moreover, 87.9% (29/33) of the CR patients with undetectable MRD (95% CI, 84.9-90.8). Grade 3 or worse adverse effects included neutropenia (100%), thrombocytopenia (100%), febrile neutropenia (90.5%), and one mortality. The median neutrophil and platelet recovery times were 13 (5-26) and 12 (8-26) days, respectively. Until Jan 30, 2023, the estimated 12-month OS, EFS, and DFS rates were 83.1% (95% CI, 78.8-87.4), 82.7% (95% CI, 79.4-86.1), and 92.0% (95% CI, 89.8-94.3), respectively.

Conclusion: Ven with DA (2 + 6) is a highly effective and safe induction therapy for adults with newly diagnosed AML. To the best of our knowledge, this induction therapy has the shortest myelosuppressive period but has similar efficacy to previous studies.

Keywords: Acute myeloid leukemia; DA; Induction treatment; Venetoclax.

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Figures

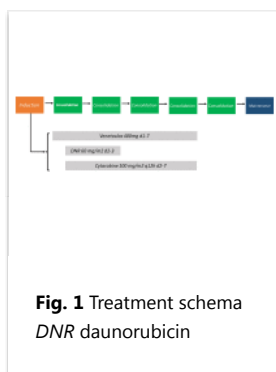


Fig. 1 Treatment schema
DNR daunorubicin

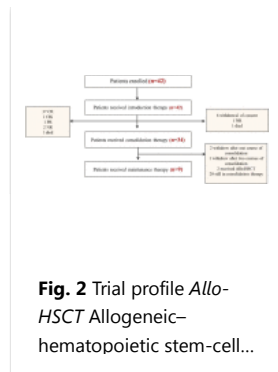


Fig. 2 Trial profile *Allo-HSCT* Allogeneic-hematopoietic stem-cell...

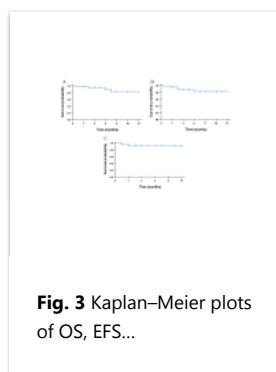


Fig. 3 Kaplan-Meier plots
of OS, EFS...

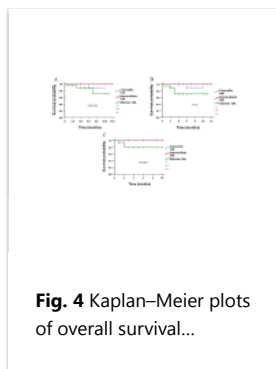


Fig. 4 Kaplan-Meier plots
of overall survival...

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