

**A Single-arm Open-label Multicenter Clinical Study
of Selinexor in Combination With HAD or CAG Rregimens
in Relapsed or Refractory Acute Myeloid Leukemia**

Project lead research unit: Shanxi Bethune Hospital

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**Board Name: Ethics Committee of Shanxi Bethune
Hospital**

Board Affiliation: Shanxi Bethune Hospital

Interventions:

1. Treatment regimen:

Selinexor (60 mg) is used twice weekly for two weeks (four times, 240 mg total of selinexor) in combination with HAD or CAG regimens for reinduction therapy in patients with relapsed and refractory AML.

The two regimens combined with selinexor included:

(Bone marrow image indicates active hyperplasia) HAD regimen: homoharringtonine (HHT) ($2\text{mg}/\text{m}^2/\text{d}$) $\times 7$ days, daunorubicin (DNR, $40\text{mg}/\text{m}^2/\text{d}$) $\times 3$ days, cytarabine (Ara-C, $100\text{--}200\text{mg}/\text{m}^2/\text{d}$) $\times 7$ days (no leukocyte-elevating drugs were applied throughout the course before and after treatment)

(Bone marrow image indicates hypoproliferation) CAG regimen: Granulocyte Colony-Stimulating Factor (G-CSF, $5\mu\text{g}/\text{kg}/\text{d}$, starting 12 hours before chemotherapy $\times 14$ days (d1-d14), aclacinomycin ($20\text{mg}/\text{d}$) $\times 4$ days (d1-4), cytarabine ($10\text{ mg}/\text{m}^2$, subcutaneous injection, once every 12 hours) $\times 14$ days (d1-d14).

G-CSF was discontinued in the CAG regimen when $\text{WBC} > 20 \times 10^9/\text{L}$, but chemotherapy was not stopped

2. Subsequent treatment regimen:

For patients eligible for allogeneic stem cell transplantation, stem cell transplantation is performed directly after treatment, and two courses (60 mg) of selinexor are maintained once a week and three weeks after transplantation;

Patients who are not eligible for transplantation or who have not undergone allogeneic stem cell transplantation should continue with

two courses of treatment with HAD or CAG regimen, and selinexor (60 mg) is used once a week for two weeks.

Supportive care:

- Platelet transfusion: Maintain platelet levels $> 20 \times 10^9/L$
- Red blood cell transfusion: keep hemoglobin $> 80 \times 10^9/L$
- Hepatoprotective drugs: routinely used in induction and consolidation therapy

Bone marrow monitoring:

[Time point]: 10 times in total. These include bone puncture every 2 months at initial diagnosis, CR and consolidation maintenance period, and every 3 months after treatment until 2 years.

[Monitoring items]: monitoring of bone marrow morphology and molecular biology indicators.