

# MRD-guided Maintenance Post-HCT: Gilteritini vs Sorafenib

NCT07463651

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 3
<b>Sponsor</b>	The First Affiliated Hospital of Soochow University
<b>Enrollment</b>	594 participants

## Key Eligibility Criteria

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### Inclusion (9)

- Informed consent and willingness to participate in this clinical study;
- Gender is not limited, age range is 14-70 years old (including threshold);
- ECOG score 0-2 points;
- Diagnosed with AML through bone marrow morphology, immunology, cytogenetics, and molecular biology (MICM) typing, and confirmed to have FLT3-ITD mutation;
- Successfully accepted allo HSCT, with no restrictions on the pre-treatment protocol, allowing any donor source \[fully matched cell, unrelated donor (URD), incompatible unrelated donor, haploidentical relative donor or umbilical cord blood\], allowing any graft source \[umbilical cord blood, bone marrow (BM), peripheral blood (PB)\]; e Patients with complete morphological remission (CR) prior to allo HSCT, and FLT3-ITD MRD positivity detected by PCR-NGS within 30 days prior to allo HSCT (defined as FLT3-ITD transcript level  $\leq 10^{-6}$ );

... and 4 more (see full listing online)

### Exclusion (10)

- Allergies to Gilteritinib or Sorafenib, as well as any components of the therapeutic drugs used during the study period;
- Any serious comorbidities that make patients unsuitable for participation in this study or may affect protocol compliance;
- FLT3-ITD molecular MRD positivity before maintenance therapy;
- Severe organ dysfunction such as organ failure occurs after allogeneic hematopoietic stem cell transplantation;
- Subjects who are positive for hepatitis B surface antigen (HBsAg) and whose hepatitis B virus (HBV) DNA titer is higher than the upper limit of the normal value range of the research center, and who are judged by the researchers not suitable for this study; Individuals with positive hepatitis C virus (HCV) antibodies and positive peripheral blood HCV RNA; Individuals who are HIV antibody positive; Positive syphilis test results;

... and 5 more (see full listing online)

## Locations (2 total)

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the First Affiliated Hospital of Soochow University, Suzhou, Jiangsu, China

Ruijin Hospital, Shanghai Jiaotong University School of Medicine, Shanghai, Shanghai Municipality, China

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<https://clinicaltrials.gov/study/NCT07463651>

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