

Pacritinib, a Kinase Inhibitor of CSF1R, IRAK1, JAK2, and FLT3, in Adults and Pediatric Participants 12 Years of Age or Older With Myelodysplastic Syndromes or Myelodysplastic/Myeloproliferative Neoplasms

NCT06303193

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	National Cancer Institute (NCI)
Enrollment	160 participants

Key Eligibility Criteria

Inclusion (35)

- Participants must have histologically or cytologically confirmed MDS or MDS/MPN, including therapy-related MDS or MDS/MPN, and MDS or MDS/MPN with germline predisposition, by the Department of Laboratory Medicine Hematology Laboratory, CC or by the Laboratory of Pathology, NCI as defined according to the 2016 WHO criteria, 2022 WHO criteria, or 2022 International Consensus Classification
 - Age 12-17 years for phase I and age ≥ 18 years for phase II
 - Participants ≥ 18 years of age with HR-MDS must have resistance to hypomethylating agents as defined as failure to show improvement after at least 4 cycles of treatment (primary resistance) or relapse in participants with initial response to long-term treatment (secondary resistance) OR have intolerance to hypomethylating agents OR have a contraindication to hypomethylating agents
 - Participants ≥ 18 years of age with LR-MDS must be refractory to or ineligible to receive standard of care therapies, i.e. erythropoietin-stimulating agents, lenalidomide, luspatercept, and present with one of the following characteristics:
 - Severe neutropenia defined by absolute neutrophils count $\leq 0.5(\sqrt{10}) \times 10^9/L$ without the use of granulocyte colony-stimulating factors
- ... and 30 more (see full listing online)

Exclusion (20)

- Participants with platelet transfusion-refractory thrombocytopenia, with inability to keep platelet threshold above 10 K/mcL with transfusions
 - Participants with evidence of ongoing hemorrhage, active signs/symptoms of bleeding, or history of severe (grade ≥ 3) unprovoked bleeding complications in the one year prior to enrollment, or any unprovoked grade 2 bleeding complications in the 3 months prior
 - to enrollment
 - Use of anti-platelet or anticoagulant medication other than low-dose aspirin (100 mg daily or less) in the 14 days prior to enrollment, or any ongoing requirement for these medications
 - Participants who are unwilling to accept blood transfusions
- ... and 15 more (see full listing online)

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States

<https://clinicaltrials.gov/study/NCT06303193>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).