For Patients with Suspected MDS

NHLBI-MDS Available Through ECOG-ACCRIN Cancer Research Group

The National Myelodysplastic Syndromes (MDS) Study

Recruiting patients with low blood counts undergoing a bone marrow assessment for evaluation of MDS

**Patient Population**

See Section 3.0 for Complete Eligibility Details

- Suspected (e.g., persistent unexplained cytopenia, circulating peripheral blasts etc.) MDS or MDS/MPN overlap disorders and undergoing diagnostic work-up with planned bone marrow assessments OR diagnosed with de novo or therapy-related MDS within 12 months of enrollment per WHO criteria and undergoing clinical evaluation and planned bone marrow assessments to confirm MDS or to evaluate disease status
- Bone marrow aspirate expected to be performed within 1 week of registration, and in all cases must be performed no later than 4 weeks after enrollment
- Age ≥ 18 years
- No prior treatment for MDS at entry and through the time of the entry bone marrow aspirate
- No treatment with hematopoietic growth factors in prior 6 months
- If anemic without prior MDS: B12, serum folate, MCV, RDW, ferritin, and iron studies performed within the prior 6 months
- No diagnosis of a solid tumor or hematologic malignancy within 2 years prior to enrollment except for in situ cancer of the skin (basal or squamous cell), cervix, bladder, breast, or prostate
- No treatment with radiation therapy in the 2 years prior to registration
- No non-hormonal treatment for malignancy within 2 years prior to registration
- No established hereditary bone marrow failure syndrome
- No known primary diagnosis of aplastic anemia, classical paroxysmal nocturnal hemoglobinuria, amegakaryocytic thrombocytopenic purpura, or large granular lymphocyte leukemia
- Not enrolled in the Connect MDS/AML Disease Registry
- Note: Alternative causes for cytopenias should be considered (see protocol for recommended tests)

**Patient Plan**

See Section 5.0 for Study Design Details

- Baseline:
  - Patient histories will be obtained and medical records will be reviewed to obtain past medical history, baseline laboratory tests, and diagnostic information (including pathology reports and treatment history)
  - Bone marrow and peripheral blood slides will be centrally reviewed (patient is required to contribute for storage and provide eyebrow hairs and buccal swab)
  - Based on central pathology review, a baseline classification will be made which will assign the participant into either
    - Longitudinal cohort:
      - MDS; MDS/MPN overlap disorders
      - AML with < 30% blasts without core binding factor or acute promyelocytic leukemia (AML with < 30% blasts including chromosomal rearrangements between chromosomes 8 and 21 and within chromosome 16 as well as t(15;17))
      - ICUS
      - Or At Risk (dysplastic or select genetic markers), or
      - The Cross-sectional cohort (no longitudinal follow-up)

- Follow-up:
  - Sites will be notified via email, no later than the 12th month post-enrollment, if follow-up is required.; however, individuals not assigned to a group by month 6 should submit specimens and data associated with that visit
  - Cross-Sectional: No post baseline biological samples/data will be collected
  - Longitudinal: Will submit specimens and data associated at each follow-up visits (occurring every 6 months)
  - Biologic samples are submitted at AML diagnosis
  - Capture of biologic samples will be discontinued if the participant receives an HCT or following AML diagnosis
  - Individuals may participate in other studies but will continue to submit data and specimens for this protocol

Refer to the Manual of Procedures (MOP) for additional details re: the procedures used for this study.

**Patient Enrollment**

All Sites: Oncology Patient Enrollment Network (OPEN) [https://open.ctsu.org](https://open.ctsu.org)

**Protocol Information**

ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

Please Enroll Your Eligible Patients!
NHLBI-MDS

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Study Schema

Eligible Participants Undergoing Medically Indicated Bone Marrow Procedure
- Suspected (e.g., persistent unexplained cytopenias, circulating peripheral blasts) MDS or MDS/MPN overlap disorders or
- Pathologic diagnosis of MDS within 12 months prior to enrollment and
- Untreated

1. Register for MDS study
2. Assign study collection kits
3. Patient care visit, samples collected for diagnosis
4. Research sample kits shipped to CL/B overnight

Pathology—ship slides to CL/B:
Whenever marrow aspirate is performed:
- 3 PB unstained, 1 W/G stain (optional)
- 3 BM aspirate unstained, 1 W/G (optional), 1 Prussian blue (optional)
- If biopsied 1 BM biopsy H&E stained, 1 unstained core section

5. Patient care pathology diagnosis
6. CL/B prepares and stores slides
7. Site enters patient care visit clinical data
8. MDS Study Assignment
   Based on central pathology review, a baseline classification of clinical data and research slides sent from site
   Cross-sectional Cohort
   All others; no follow-up visits or specimen collection

Longitudinal Cohort
Participants with MDS, MDS/MPN overlap disorders, AML cases with < 30% blasts without core binding factor or acute promyelocytic leukemia (including chromosomal rearrangements between chromosomes 8 and 21 and within chromosome 16 as well as [15;17]) or ICUS or At Risk (dysplastic or genetic markers)*
Data and specimens collected every 6 mo; follow-up visits, when aspirates performed and if participant progresses to AML

Planned enrollment: Up to 2,000 participants

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Sponsored by the National Heart, Lung, and Blood Institute in collaboration with the National Cancer Institute