NCI Community Oncology Research Program

NHLBI-MDS

For Patients with Suspected MDS

NHLBI-MDS Available Through ECOG-ACRIN 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 grown factors in prior 6 months
- If anemic without prior MDS: B12, serum folate, MCV, RDW, ferritin, and iron studies tests 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.

Study Chair:
Mikkael Sekeres, M.D., M.S.

Deputy Chair:
Steven Gore, M.D.

Patient Enrollment

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

Protocol Information

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

Please Enroll Your Eligible Patients!

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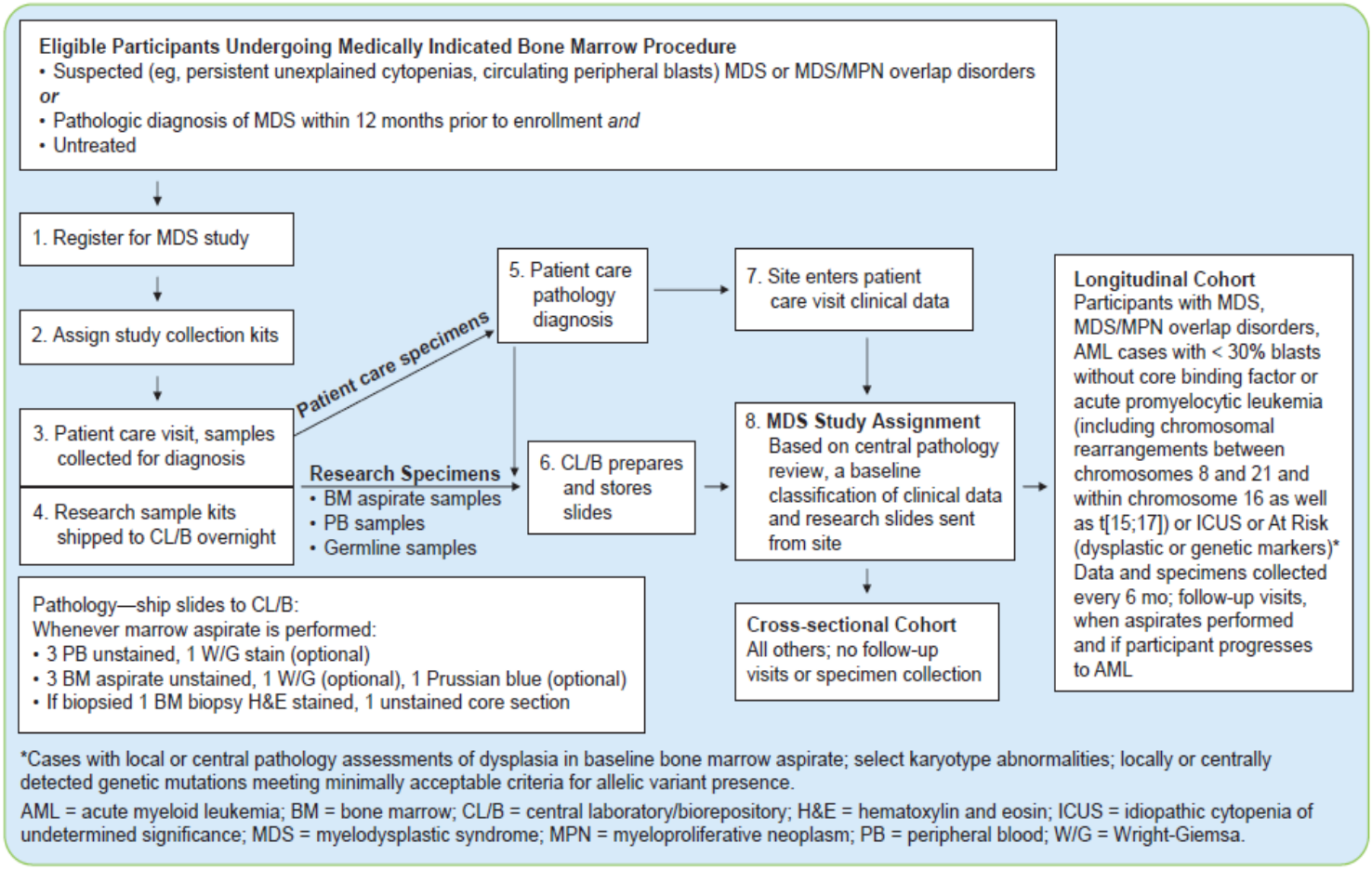
Study Schema



*Cases with local or central pathology assessments of dysplasia in baseline bone marrow aspirate; select karyotype abnormalities; locally or centrally detected genetic mutations meeting minimally acceptable criteria for allelic variant presence.

AML = acute myeloid leukemia; BM = bone marrow; CL/B = central laboratory/biorepository; H&E = hematoxylin and eosin; ICUS = idiopathic cytopenia of undetermined significance; MDS = myelodysplastic syndrome; MPN = myeloproliferative neoplasm; PB = peripheral blood; W/G = Wright-Giemsa.

Planned enrollment: up to 3,500 participants

MDS The National Myelodysplastic Syndromes Natural History Study

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

ECOG-ACRIN cancer research group

Reshaping the future of patient care