

ELEMENT-MDS: A Study to Compare the Efficacy and Safety of Luspatercept in Participants With Myelodysplastic Syndrome (MDS) and Anemia Not Receiving Blood Transfusions

NCT05949684

Status	RECRUITING
Phase	Phase 3
Sponsor	Bristol-Myers Squibb
Enrollment	360 participants

Key Eligibility Criteria

Inclusion (8)

- Participant has documented diagnosis of MDS according to World Health Organization (WHO) 2016 that meet IPSS-R classification of very low, low, or intermediate-risk disease, (intermediate-risk of d 3.5 IPSS-R score) confirmed via bone marrow aspirate and:.
 - i) \leq 5% blasts in bone marrow and \leq 1% blasts in peripheral blood.
 - Participant is not transfusion dependent (NTD) based on IWG2018 criteria.
 - Participant is erythropoiesis-stimulating agent naive. Participants may be randomized at the investigator's discretion if the participant received no more than 2 prior doses of epoetin alfa, epoetin alfa biosimilar, or darbepoetin alfa, with the last dose at least 8 weeks prior to randomization.
 - Participant has a baseline endogenous serum erythropoietin (sEPO) level of \geq 500 U/L.
- ... and 3 more (see full listing online)

Exclusion (4)

- Participant with secondary MDS (that is, MDS that is known to have arisen as the result of chemical injury or treatment with chemotherapy and/or radiation for other diseases).
- Participant with known history of diagnosis of AML.
- Participant with history of cerebrovascular accident (including ischemic, embolic, and hemorrhagic cerebrovascular accident), transient ischemic attack, deep venous thrombosis (including proximal and distal), pulmonary or arterial embolism, arterial thrombosis, or other venous thrombosis within 6 months prior to randomization.
- Participant with a history of pure red cell aplasia and/or antibody against erythropoietin.

Locations (169 total)

Community Cancer Institute, Clovis, California, United States
Compassionate Cancer Care Medical Group, Fountain Valley, California, United States
Local Institution - 0095, Fresno, California, United States
... and 166 more locations