

Titolo:	PIRAMIDH tA Phase 3, Multicenter, Open Label, Randomized, Non-comparative Two-arm Study of Ivosidenib (IVO) Monotherapy and Azacitidine (AZA) Monotherapy in Adult Patients With Hypomethylating Agent (HMA) Naive Myelodysplastic Syndromes (MDS) With an Isocitrate Dehydrogenase-1 (IDH1) Mutation (PyramIDH Study)
Patologia:	mielodisplasia
Tipo di Studio:	interventistico
Fase:	Fase III randomizzato
Principali criteri di inclusione:	Diagnosis of HMA naive IDH1 R132 mutated MDS defined according to WHO criteria (5th edition): Moderate high, high and very high-risk MDS per IPSS-M score will be eligible regardless of blood counts and with blast counts 0-19%. Low and moderate low-risk MDS per IPSS-M score must: Have cytopenias related to MDS, defined as: <100 platelets/microliter, or absolute neutrophil count (ANC) <1000/mm³, or hemoglobin <10g/dL AND Have a blast count between 5-19% AND Be eligible for HMA therapy (very low risk participants are to be excluded)
Principali criteri di esclusione:	Received prior anticancer/disease modifying treatment for MDS (including HMA's, cytotoxic chemotherapy, investigational agents, bcl-2 inhibitor based-regimens, hematopoietic stem cell transplant (HSCT), IDH1 inhibitors). For LR-MDS patients, prior treatment with growth factors, luspatercept, lenalidomide, and imetelstat are allowed. >20% blasts by morphology or immunohistochemistry on screening bone marrow aspirate/biopsy
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