

High-risk del 5q myeloid disease

Proposal for a protocol by Prof. E. Hellström-Lindberg

ELN discussion 2006

- Patients with MDS IPSS Int-2 / High or AML with a karyotype including deletion 5q have an overall poor prognosis due to
 - Short survival, untreated
 - Lower than average CR rate to induction chemotherapy
 - Higher than average relapse rate after allo SCT
- Lenalidomide has shown activity in "low-risk" MDS with complex karyotype including del5q

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Proposal for a protocol

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- Eligible patients (all with a karyotype including del 5q (or those who lack 5q31?))
 1. High-risk MDS and AML not suitable for induction chemotherapy
 2. High-risk MDS and AML, refractory to induction chemotherapy
 3. High-risk MDS and AML, relapsing after induction chemotherapy
 4. Myeloid disease with del 5q relapsing after allo SCT
- Treatment: Lenalidomide according to a dose finding schedule. 8-12 weeks
- Possibility of adding another drug, e.g. hypomethylation in case of no response

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- Participants
 - ELN WP 5 and 8
 - European Study Groups for MDS / AML
- Since there most likely are competing studies ongoing, the different study groups could chose from the different eligibility groups
- Overall platform, support and trial registry: ELN
- Local management (ethics, MPA, etc) by study group