

REGISTRATION & RANDOMIZATION FORM (1)

Instructions: Please complete this form before randomization to check eligibility. Randomize via Internet through TOP (<https://www.hdc.hovon.nl/top>) or send this form by fax or report by telephone to HOVON Data Center. Fax +31.10.7041028. Tel +31.10.7041560. Any mistake in patient characteristics or eligibility as given at registration must be reported by sending the revised form to: HOVON Data Center, Erasmus MC - Daniel den Hoed, P.O. Box 5201, 3008 AE ROTTERDAM, The Netherlands.

Patient namecode: Hospital: Patient study number: |__|__|__|

PATIENT DATA

Caller (who registers the patient) 8

Responsible physician 9

Date of birth [dd/mm/yyyy] 11 |__||__||__||

Sex 12 |__| 1=male 2=female

Normal or any cytogenetic abnormalities (including del(5q) abnormalities) 16 |__| 0=normal 1=del(5q) abnormality
2=other abnormality 3=not yet known

Date of written informed consent [dd/mm/yyyy] 17 |__||__||__||

PATIENT GIVES CONSENT FOR:

Central tissue review (Hematocytology Review) 18 |__| 0=no 1=yes

Blood and/or bone marrow samples for side studies 19 |__| 0=no 1=yes

ELIGIBILITY

MDS WHO diagnosis 20 |__| 1=RA 2=RARS 3=RCMD
4=RCMD-RS 5=RAEB-1 6=MDS-U
7=CMML-1 (WBC $\leq 12 \times 10^9/l$)
8=MDS, WHO yet unknown

MDS FAB diagnosis 21 |__| 1=RA 2=RARS
3=RAEB (<10% myeloid blasts)
4=CMML (<10% myeloid blasts and
WBC $\leq 12 \times 10^9/l$)
5=MDS, FAB yet unknown

IPSS score 22 |__|. |__|

Hemoglobine [mmol/l] 23 |__|_|__|. |__|

OR 24 |__|_|__|. |__|

[g/dl]

ANC [x10⁹/l] 25 |__|_|__|_|__|. |__|

Red blood cell transfusion dependent (≥ 2 units RBC during at least 8 weeks; units must be given for a Hb ≤ 5.6 mmol/l) 26 |__| 0=no 1=yes

Age ≥ 18 years 27 |__| 0=no 1=yes

WHO performance status 0, 1 or 2 (see protocol Appendix D) 28 |__| 0=no 1=yes

Failure of response or relapse after hematological improvement or disease progression to maximal RAEB-1 after previous therapy with Epo/G-CSF (if no previous Epo/G-CSF, choose 'not applicable') 29 |__| 0=no 1=yes 2=not applicable

Date: |__||__||__|| Name: Signature:

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Serum erythropoietin level > 200U/l
 or ≤ 200 U/l if failure of response or loss of hematological
 improvement or disease progression to maximal RAEB-1 after
 prior standard therapy with Epo/G-CSF 30 |__| 0=no 1=yes

Predictive score to respond on standard treatment with
 Epo/G-CSF according to guidelines (see appendix H) 31 |__| 0=score 0 1=score 1
 2=score 2 3=not applicable

Serum creatinin < 150 µmol/l 32 |__| 0=no 1=yes

Serum bilirubin < 25 µmol/l and ASAT, ALAT and Alkaline
 Phosphatase < 2.5 x ULN, except if related to disease 33 |__| 0=no 1=yes

Written informed consent 34 |__| 0=no 1=yes

Negative pregnancy test within 7 days prior to start of study drug 35 |__| 0=no 1=yes 2=not applicable

Patient (all men, pre-menopausal women) agrees to use adequate
 contraceptive methods 36 |__| 0=no 1=yes 2=not applicable

Severe cardiac, pulmonary, neurologic, metabolic or psychiatric
 diseases or active malignancies 37 |__| 0=no 1=yes

Anemia due to other causes than MDS including iron, B12 and
 folate deficiencies, autoimmune hemolysis and/or paroxysmal
 nocturnal hemoglobinuria (PNH) 38 |__| 0=no 1=yes

Hypoplastic MDS 39 |__| 0=no 1=yes

MDS with Jak2 mutations 40 |__| 0=no 1=yes 2=not yet known

Active uncontrolled infection 41 |__| 0=no 1=yes

Patients dependent on platelet transfusions or with platelet counts
 < 25 x 10⁹/l or with active bleeding 42 |__| 0=no 1=yes

Patients treated with biological response modifiers (i.e. growth
 factors, immunosuppressive agents and/or chemotherapy) within 1
 month prior to randomization 43 |__| 0=no 1=yes

Lactating women 44 |__| 0=no 1=yes

Prior treatment with lenalidomide 45 |__| 0=no 1=yes

Prior CTCAE ≥ grade 3 allergic reaction/hypersensitivity to
 thalidomide 46 |__| 0=no 1=yes

Prior CTCAE ≥ grade 3 rash/blistering while taking thalidomide 47 |__| 0=no 1=yes

Prior CTCAE ≥ grade 3 allergic/hypersensitivity to Epo and/or G-
 CSF 48 |__| 0=no 1=yes

Date: |__|/|__|/|__|

Name:

Signature:

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DATA FROM HOVON DATA CENTER

Date of randomization..... [dd/mm/yyyy] 14 |__||__||____|

Patient study number..... 1 |__|__|__|

Treatment arm allocated..... 13 |__| 1=Arm A: lenalidomide monotherapy
2=Arm B: lenalidomide ± Epo ± G-CSF

Date: |__||__||____| Name: Signature: