A Phase II randomized multicenter study to assess the efficacy of lenalidomide with or without erythropoietin and granulocyte-colony stimulating factor in patients with low and intermediate-1 risk myelodysplastic syndrome.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20915

Source
NTR

Brief title
HOVON 89 MDS

Health condition

Myelodysplastic syndrome (MDS)

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON) P/a HOVON Data CenterErasmus MC - Postbus 2040; 3000 CA Rotterdam; Tel: +31 10 704 1560 Fax: +31 10 704 1028; e-mail: hdc@erasmusmc.nl
Source(s) of monetary or material Support: Amgen, BSP, Johnson&Johnson-Orthobiotech, Roche, Novartis and Celgene. Dutch Cancer Society (KWF)

Intervention

Outcome measures

Primary outcome

Hematological improvement (HI) according to IWG 2006 criteria.

Secondary outcome

1. Adverse events of CTCAE >= grade 2;

2. Time-to-HI and duration-of-HI;

3. Number of given treatment cycles per patient, and especially for arm B the number of patients receiving Epo and/or G-CSF;

4. Response rate (in terms of CR, PR, including cytogenetic response according to the modified response criteria of the IWG for MDS).

5. Progression-free-survival;

6. Leukemic evolution. The risk of leukemic evolution will be calculated with competing risk death without previous evolution
7. Number of transfusions of red blood cells and duration of RBC transfusion independence.

Study description

Background summary

Study phase: Phase II.

Study objective:
To evaluate the efficacy of lenalidomide (Revlimid) in low/intermediate-1 risk MDS with or without treatment with Epo (NeoRecormon)/G-CSF (Neupogen).
To evaluate the safety and tolerability of lenalidomide (Revlimid) in low/intermediate-1 risk MDS with or without Epo (NeoRecormon)/G-CSF (Neupogen).

Patient population: Patients with low/intermediate-1 risk myelodysplastic syndrome.

Study design: Prospective, multicenter, open label, randomized.

Duration of treatment: Minimum of 6 months for arm A and 12 months for arm B or until relapse or disease progression; continuation thereafter if responsive. All patients will be followed until 5 years after registration.

Study objective

The hypothesis to be tested is that the outcome in arm B is better than in arm A.

Study design

1. At entry;

2. After each induction cycle;

3. After each maintenance cycle;

4. During follow up: every 6 months.

Intervention

Arm A: 12 cycles of lenalidomide, followed by lenalidomide maintenance cycles.

Arm B: 4 cycles of lenalidomide, followed by 4 cycles of lenalidomide +/- Epo; followed by 4 cycles of lenalidomide +/- Epo +/- G-CSF, followed by lenalidomide +/- Epo +/- G-CSF maintenance cycles.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with MDS classified as:

RA, RARS and RAEB (with <10% myeloid blasts), CMML (with <10% myeloid blasts), according to FAB, or;

RA, RARS, RCMD, RCMD-RS, RAEB-1, MDS-U according to WHO, or;

patients with MPD/MDS (CMML-1 according to WHO) with a WBC <= 12x10^9/l, with an IPSS <= 1.0.

2. Hb <= 6.2 mmol/l (10.0 g/dl) or Hb <= 7.2 mmol/l and ANC <= 1.0x10^9/l or red blood cell transfusion dependent;

3. Age >= 18 years;

4. WHO performance status 0-2;

5. Patient not previously treated with Epo/G-CSF, or failure of response or relapse after hematological improvement or disease progression to maximal RAEB-1 after previous therapy with Epo/G-CSF;

6. Serum creatinin < 150 µmol/l;

7. Serum billirubin < 25 µmol/l and ASAT, ALAT and Alkaline phosphatase < 2.5 times the upper limit of normal, except if related to disease;

8. The patient must give written informed consent;

9. Negative pregnancy test within 7 days prior to start of study drug, if applicable;

10. Patient (all men, pre-menopausal women) agrees to use adequate contraceptive methods;

11. Serum erythropoietin level > 200 U/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; Epo/G-CSF should be stopped at least 1 month before randomization.

Exclusion criteria

1. Severe cardiac, pulmonary, neurologic, metabolic or psychiatric diseases or active malignancies;

2. Anemia due to other causes than MDS including iron, B12 and folate deficiencies, auto-immune hemolysis and/or paroxysmal noctural hemoglobinuria (PNH);

3. Hypoplastic MDS;

4. High predictive score (score 0 or 1) to respond on standard treatment with Epo/G-CSF according to guidelines;

5. Active uncontrolled infection;

6. Absolute neutrophil count (ANC) < 0.5x10^9/l;

7. Patients dependent on platelet transfusions or with platelet counts < 25x10^9/l or patients with active bleeding;

10. Patients treated with biological response modifiers (i.e. growth factors, immunosuppressive agents and/or chemotherapy) within 1 month prior to randomization;

11. Lactating women;

12. Prior treatment with lenalidomide;

13. Prior CTCAE >= grade 3 allergic reaction/hypersensitivity to thalidomide;

14. Prior CTCAE >= grade 3 rash/blistering while taking thalidomide
15. Prior CTCAE >= grade 3 allergic/hypersensitivity to Epo and/or G-CSF

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2009
Enrollment:	200
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-05-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1715
NTR-old	NTR1825

Register	ID
Other	EudraCT number : 2008-002195-10
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A