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.

Gepubliceerd: 19-05-2009 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20915

Bron
NTR

Verkorte titel
HOVON 89 MDS

Aandoening

Myelodysplastic syndrome (MDS)

Ondersteuning

Primaire 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
Overige ondersteuning: Amgen, BSP, Johnson&Johnson-Orthobiotech, Roche, Novartis and Celgene. Dutch Cancer Society (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Hematological improvement (HI) according to IWG 2006 criteria.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

1. At entry;

2. After each induction cycle;

3. After each maintenance cycle;

4. During follow up: every 6 months.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2009
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-05-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1715
NTR-old	NTR1825
Ander register	EudraCT number : 2008-002195-10
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A