A randomized phase III study on the effect of Thalidomide combined with Adriamycin, Dexamethasone (AD) and High Dose Melphalan in patients with multiple myeloma.

Gepubliceerd: 06-09-2005 Laatst bijgewerkt: 18-08-2022

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-OMON27202

Bron
NTR

Verkorte titel
HOVON 50 MM / GMMG-HD3

Aandoening

Multiple Myeloma.

Ondersteuning

Primaire sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
P/a HOVON Data Center
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Overige ondersteuning: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
Koningin Wilhelmina Fonds (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Event free survival (i.e., time from registration to induction failure, progression or death, whichever occurs first); the time to failure of patients with induction failure is set at one day.
Patients are considered induction failure when they have not achieved at least a PR and are not eligible for further treatment according to protocol.

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase:

Phase III

Study objectives:

Evaluation of the effect of Thalidomide in addition to AD and High Dose Melphalan.

Patient population:

Patients with multiple myeloma, previously untreated, Salmon & Durie stage II or III, age 18-65 years inclusive.

Study design:

Prospective, multicenter, randomized.

Duration of treatment:

Expected duration of induction, stem cell collection and intensification (with or without Thalidomide) is 5 - 7 months.

Thalidomide will be continued as maintenance until relapse or progression; however it will be discontinued early when the patient has not at least a PR 3 months after Melphalan. In patients not randomized to Thalidomide, maintenance therapy with a-Interferon will be given until relapse or progression.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients with multiple myeloma, meeting all eligibility criteria will be randomized on entry between:

Arm A:
standard Vincristine, Adriamycin and Dexamethasone (VAD) induction, followed by intensive chemotherapy with High-dose Melphalan, followed by maintenance therapy with alpha-interferon.

Arm B:

induction chemotherapy with Thalidomide, Adriamycin and Dexamethasone (TAD) followed by intensive chemotherapy with High-dose Melphalan, followed by maintenance with Thalidomide.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with a confirmed diagnosis of multiple myeloma stage II or III according to the Salmon & Durie criteria;

2. Age 18-65 years inclusive;

3. WHO performance status 0-3;

4. Negative pregnancy test at inclusion if applicable;

5. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known intolerance of Thalidomide;

2. Systemic AL amyloidosis;

3. Previous chemotherapy or radiotherapy except 2 cycles of Melphalan/Prednisone or local radiotherapy in case of local myeloma progression;

4. Severe cardiac dysfunction (NYHA classification II-IV);

5. Significant hepatic dysfunction (serum bilirubin >= 30 micromol/l or transaminases >= 2.5 times normal level), unless related to myeloma;

6. Patients known to be HIV-positive;

7. Patients with active, uncontrolled infections;

8. Patients with a history of active malignancy during the past 5 years with the exception of basal carcinoma of the skin or stage 0 cervical carcinoma;

9. Patients who are not willing or capable to use adequate contraception during the therapy (all men, all pre-menopausal women);

10. Patients <= 55 years with an HLA-identical sibling who will undergo myeloablative AlloSCT.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	27-11-2001
Aantal proefpersonen:	450
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-09-2005
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	NL201
NTR-old	NTR238
Ander register	: HO50
ISRCTN	ISRCTN06413384

Resultaten

Samenvatting resultaten
Haematologica. 2008 Jan;93(1):124-7.

2 voorafgaande onderzoeken:

M.C. Minnema, I. Breitkreutz, J.J. Auwerda, B. van der Holt, F.W. Cremer, A.M. van Marion, P.H. Westveer, P. Sonneveld, H. Goldschmidt and H.M. Lokhorst. Prevention of venous thromboembolism with low molecular-weight heparin in patients with multiple myeloma treated with thalidomide and chemotherapy. Leukemia, 18(12), 2044-2046. 2004

H. Goldschmidt, P. Sonneveld, F.W. Cremer, B. van der Holt, P. Westveer, I. Breitkreutz, A.

Benner, A. Glasmacher, I.G.D. Schmidt-Wolf, H. Martin, D. Hoelzer, A.D. Ho and H.M. Lokhorst. Joint HOVON-50/ GMMG-HD3 randomized trial on the effect of thalidomide as part of a high-dose therapy regimen and as maintenance treatment for newly diagnosed myeloma patients. Annals of Hematology, 82, 654-659. 2003