A randomized phase II study for evaluation of T cell depleted non myeloablative allogeneic stem cell transplantation followed by early consolidation with lenalidomide or lenalidomide combined with bortezomib and subsequent DLI for patients with multiple myeloma in progression or relapse following first line therapy.

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For each of the two treatment arms separately: 1. Null hypotheses (H0): Failure free duration (FFD) at 9 months post allo-SCT = 50%; 2. Alternative hypotheses (H1): FFD at 9 months post allo-SCT = 70%.

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

Samenvatting

ID

NL-OMON26950

Bron
NTR

Verkorte titel
HOVON 108 MM

Aandoening

Multiple Myeloma (Kahler¡¯s disease)

Ondersteuning

Primaire sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
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In addition HOVON is supported by the Dutch Cancer Society.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Assessment of feasibility and toxicity of T cell depleted NMA Allo-SCT followed by lenalidomide or lenalidomide combined with bortezomib, and subsequent DLI; as treatment of relapsed multiple myeloma.

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase: II.

Study objective:

Primary objective: Assessment of feasibility and toxicity of T cell depleted NMA Allo-SCT followed by lenalidomide or lenalidomide combined with bortezomib, and subsequent DLI; as treatment of relapsed multiple myeloma.

Secondary objectives:

1. To investigate the efficacy of this regimen in terms of complete remission rate, overall and progression free survival;

2. To evaluate quality of life with these regimens.

Study design:

Prospective, multi center, randomized.

Duration of treatment:

9 months. Subsequently patients will be followed until 5 years after registration.

Doel van het onderzoek

For each of the two treatment arms separately:

1. Null hypotheses (H0): Failure free duration (FFD) at 9 months post allo-SCT = 50%;

2. Alternative hypotheses (H1): FFD at 9 months post allo-SCT = 70%.

Onderzoeksopzet

1. At entry: Within three weeks before Allo-SCT;

2. Within 2 weeks before first day of first consolidation cycle with lenalidomide and/or bortezomib;

3. During each cycle of lenalidomide and/or bortezomib;

4. Within two weeks before DLI and monthly after DLI;

5. During follow up every two months. All patients will be followed until 5 years after registration.

Onderzoeksproduct en/of interventie

T cell depleted NMA Allo-SCT followed by 3 cycles of lenalidomide 10 mg/daily or lenalidomide 10 mg/daily combined with weekly bortezomib 1.3 mg/m2, and preemptive DLI. The conditioning of NMA Allo-SCT is performed with melphalan/fludarabine and in vitro and in vivo T cell depletion with Alemtuzumab (for MUD in combination with ciclosporin).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with multiple myeloma with a first relapse or progression after first line therapy;

2. Relapsed or progressive patients have received reinduction therapy before entering this trial;

3. SD or better response after reinduction treatment;

4. 18-65 years,inclusive;

5. HLA-identical sibling or unrelated donor completely matched (10/10) (excluding identical twins);

6. WHO-performance status 0-2;

7. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous Allo-SCT;

2. Severe pulmonary dysfunction (CTCAE grade III-IV, see appendix D);

3. Severe neurological or psychiatric disease;

4. Patients with neuropathy, CTC grade 2 or higher;

5. Significant hepatic dysfunction (serum bilirubin or transaminases ≥ 3 times upper limit of normal);

6. Significant renal dysfunction (creatinine clearance < 30 ml/min after rehydration);

7. Concurrent severe and/or uncontrolled medical condition (e.g. uncontrolled diabetes, infection, hypertension, cancer, etc.);

8. History of active malignancy during the past 5 years with the exception of basal carcinoma of the skin or carcinoma in situ of the cervix or breast;

9. Patient known to be HIV-positive;

10. Patients with brain disease with the exception of those patients whose brain disease has been treated with either radiotherapy or surgery and remains asymptomatic, with no active brain disease, as shown by CT scan or MRI, for at least 6 months;

11. The development of erythema nodosum if characterized by a desquamating rash while taking thalidomide, lenalidomide or borium;

12. Pregnant or breast-feeding female patients. Negative pregnancy test at study is mandatory for female patients of childbearing potential;

13. Not able and not willing to use adequate contraception during therapy;

14. Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and follow-up schedule;

15. Severe cardiac dysfunction (NYHA classification II-IV).

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2011
Aantal proefpersonen:	110
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-06-2011
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	NL2817

Register	ID
NTR-old	NTR2958
Ander register	HOVON : HO108
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A