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.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26950

Source
Nationaal Trial Register

Brief title
HOVON 108 MM

Health condition

Multiple Myeloma (Kahler¡¯s disease)

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)

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Intervention

Outcome measures

Primary outcome

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 outcome

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 description

Background summary

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.

Study objective

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%.

Study design

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.

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2011
Enrollment:	110
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-06-2011
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	NL2817

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

Study results

Summary results
N/A