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

No registrations found.

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

Summary

ID

NL-OMON27202

Source
Nationaal Trial Register

Brief title
HOVON 50 MM / GMMG-HD3

Health condition

Multiple Myeloma.

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
P/a HOVON Data Center
Erasmus MC - Daniel den Hoed
Postbus 5201
3008 AE Rotterdam
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Source(s) of monetary or material Support: Stichting Hemato-Oncologie voor

Volwassenen Nederland (HOVON)
Koningin Wilhelmina Fonds (KWF)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Response (PR and CR);

2. Overall survival measured form the time of registration. Patient still alive or lost to follow up are censored at the date they were last known to be alive;

3. Progression free survival (duration of the first response (PR or CR)) measured from the time of achievement of PR (or CR) to date of progression or death from any cause (whichever occurs first);

4. Toxicities of Thalidomide and chemotherapy.

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

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):	27-11-2001
Enrollment:	450

Type:	Actual

Ethics review

Positive opinion

Date:	06-09-2005
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	NL201
NTR-old	NTR238
Other	: HO50
ISRCTN	ISRCTN06413384

Study results

Summary results

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