Randomized phase III trial in elderly patients with previously untreated symptomatic Multiple Myeloma comparing MP-Thalidomide (MP-Thal) followed by thalidomide maintenance versus MP-Lenalidomide (MP-Len) followed by maintenance with lenalidomide.

No registrations found.

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

Summary

ID

NL-OMON25186

Source
Nationaal Trial Register

Brief title
HOVON 87 MM

Health condition

Multiple Myeloma

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON) P/a HOVON Data Center; Erasmus MC; Postbus 2040; 3000 CA Rotterdam Tel: +31 10 704 1560; Fax +31 10 704 1028 e-mail: hdc@erasmusmc.nl

Source(s) of monetary or material Support: HOVON receives unrestricted grants and/or financial support from Amgen, BSP, Johnson&Johnson-Orthobiotech, Roche, Novartis and Celgene for the execution of investigator sponsored trials.
In addition HOVON is supported by the Dutch Cancer Society.

Intervention

Outcome measures

Primary outcome

1. Progression free survival, defined as time from registration to progression or death from any cause;

2. Response rate (sCR, CR or VGPR).

Secondary outcome

1. Response rate (sCR, CR, VGPR or PR);

2. Overall survival, measured from time of registration;

3. Quality of response during maintenance, measured as improvement of response (from start maintenance till progression);

4. Time to maximum response, defined as time from registration to maximum response;

5. Time to death from relapse/progression (after initial response), measured from time of first relapse/progression;

6. Safety and toxicity as defined by type, frequency and severity of adverse events as defined by the National Cancer Institute (NCI) Common Terminology Criteria (CTC), version 3.0;

7. Quality of life as defined by the EORTC QLQ-C30 definitions.

Study description

Background summary

Study phase:

Randomized phase III

Study objective:

To compare progression free survival with MP+Thalidomide (MP-Thal) followed by maintenance with thalidomide versus MP+Lenalidomide (MP-Len) followed by maintenance with lenalidomide.

To compare (stringent) complete and very good partial response with MP-Thal versus MP-Len.

To compare overall survival with MP-Thal versus MP-Len.

To assess and compare overall response and time-to-response with MP-Thal versus MP-Len.

To assess the effect of maintenance therapy with thalidomide alone following MP-Thal induction or lenalidomide alone following MP-Len induction.

To assess and compare the time from relapse/progression (after initial response) to death in patients having been treated with MP-Thal versus MP-Len.

To asses the quality of life with these regimens.

To assess the safety and toxicity of both regimens.

Patient population:

Previously untreated symptomatic patients with MM. Age >65 or <= 65 and patient ineligible for high dose therapy and peripheral stem cell transplantation.

Study design:

Prospective, multicenter, randomized

Duration of treatment:

Expected duration of induction treatment: 9 months. Maintenance therapy with lenalidomide or thalidomide will be given until relapse/progression. All patients will be followed until 10 years after registration.

Study objective

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

Study design

1. At entry;

2. Before start of treatment;

3. During induction therapy;

4. After 1, 3, 5 ,7 and 9 cycles;

5. During maintenance therapy every 2 months.

Intervention

Arm A: 9 cycles of MP-Thal, followed by thalidomide maintenance.

Arm B: 9 cycles of MP-Len, followed by lenalidomide maintenance.

Contacts

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Eligibility criteria

Inclusion criteria

1. Previously untreated patients with a confirmed diagnosis of symptomatic multiple myeloma according to IMWG criteria ;

2. Age > 65 years or patients <= 65 not eligible for high dose chemotherapy and peripheral

stem cell transplantation;

3. WHO performance status 0-3 for patients <75 years and WHO performance status 0-2 for patients >= 75 years;

4. Measurable disease as defined by the presence of M-protein in serum or urine or proven plasmacytoma by biopsy;

5. Written informed consent.

Exclusion criteria

1. Non-secretory MM;

2. Known hypersensitivity to thalidomide;

3. Systemic AL amyloidosis;

4. Polyneuropathy, grade 2 or higher;

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

6. Severe pulmonary dysfunction;

7. Significant hepatic dysfunction (total bilirubin >= 30 ¦Ìmol/l or transaminases >= 3 times normal level), unless related to Myeloma;

8. Creatinine clearance <30 ml/min;

9. Patients with active, uncontrolled infections;

10. Pre-treatment with cytostatic drug, IMIDs or proteasome inhibitors;

11. Radiotherapy or a short course of steroids (e.g. 4 day treatment of dexamethasone 40 mg/day or equivalent) are allowed;

12. Patients known to be HIV-positive History of active malignancy during the past 5 years, except basal carcinoma of the skin or stage 0 cervical carcinoma;

13. Not able and/or not willing to use adequate contraception.

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):	25-02-2009
Enrollment:	668
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-01-2009
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	NL1552
NTR-old	NTR1630
Other	EudraCT nummer : 2007-004007-34
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A