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.

Gepubliceerd: 13-01-2009 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-OMON25186

Bron
Nationaal Trial Register

Verkorte titel
HOVON 87 MM

Aandoening

Multiple Myeloma

Ondersteuning

Primaire 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;

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In addition HOVON is supported by the Dutch Cancer Society.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Progression free survival, defined as time from registration to progression or death from any cause;
2. Response rate (sCR, CR or VGPR).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	25-02-2009
Aantal proefpersonen:	668
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-01-2009
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	NL1552
NTR-old	NTR1630
Ander register	EudraCT nummer : 2007-004007-34
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A