Phase I/II trial of Lenalidomide plus Bortezomib combined with Dexamethasone in patients in 1st relapse or primary refractory after first line therapy for Multiple Myeloma.

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Phase II part: - Null hypothesis (H0): (s)CR+VGPR rate = 15% - Alternative hypothesis (H1): (s)CR+VGPR rate = 30%

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

Samenvatting

ID

NL-OMON23532

Bron
NTR

Verkorte titel
HOVON 86 MM

Aandoening

Multiple Myeloma, 1st relapse or refractory after first line therapy

Ondersteuning

Primaire sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Phase I Primary endpoint
- Dose-limiting toxicity (DLT), maximum tolerated dose (MTD) and recommended phase II dose (RDL) of Bortezomib and of Lenalidomide when combined with Dexamethasone.

Phase II Primary endpoint
- (s)CR+VGPR rate. In order for patients to be considered as a success for the primary endpoint, a VGPR or (s)CR must be documented according to criteria in appendix B. All other patients will be considered as not having achieved at least a VGPR. In this analysis we will consider the best response obtained during induction/consolidation chemotherapy.

Toelichting onderzoek

Achtergrond van het onderzoek

Study phase: Phase I - II

Study objective:

Evaluation of the effect of Bortezomib combined with Lenalidomide in addition to Dexamethasone for induction and the effect of Lenalidomide alone for maintenance treatment

Patient population:
Patients with multiple myeloma, in 1st relapse or refractory after first line therapy, Salmon & Durie stage II or III, age 60-85 years inclusive

Study design:
Prospective, multicenter
Duration of treatment: Expected duration of induction is 6 - 7 months. Maintenance therapy with Lenalidomide will be given until relapse/progression. All patients will be followed until 5 years after registration or, for patiens who are still on maintenance at that moment, until

completion of maintenance therapy

Doel van het onderzoek

Phase II part:

- Null hypothesis (H0):

(s)CR+VGPR rate = 15%

- Alternative hypothesis (H1):

(s)CR+VGPR rate = 30%

Onderzoeksopzet

- At entry

- After each induction cycle (Expected duration of induction is 6 - 7 months.)

- During maintenance and follow up: every 2 months. (All patients will be followed until 5 years after registration or, for patiens who are still on maintenance at that moment, until completion of maintenance therapy
)

Onderzoeksproduct en/of interventie

During the phase I part of the study, the MTD and RDL of Bortezomib and Lenalidomide with Dexamethasone will be determined according to a slightly modified `3 + 3' dose-escalation scheme, as illustrated in the figure below. A maximum of 4 dose levels will be evaluated.

When the phase I part has established the RDL of Bortezomib and Lenalidomide for the phase II study, all further included patients will be treated with Bortezomib and Lenalidomide at the RDL, combined with Dexamethasone.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Multiple Myeloma Salmon/Durie stage II/III A+B

2. Primary refractory to or first relapse after previous objective response (PR, VGPR, CR) on standard first-line treatment

3. Age 60 – 85 years inclusive

4. Not a candidate for high-dose therapy

5. Measurable disease, i.e., serum M-component (>10 g/l), or urinary light-chain excretion (>200mg/24h),or abnormal FLC ratio with involved free light chain (FLC) > 100 mg/l or proven plasmacytoma by biopsy

6. Able and/or willing to use adequate contraceptives (especially male patients)

7. Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Prior therapy with Bortezomib or Lenalidomide

2. History of allergic reaction attributable to compounds containing boron or mannitol

3. Peripheral neuropathy or neuropathic pain Grade 2 or higher as defined by NCI CTCAE version 3

4. AL amyloidosis

5. Uncontrolled or severe cardiovascular disease

6. Impaired hepatic or renal function

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

8. Known HIV positivity

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-09-2008
Aantal proefpersonen:	72
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-09-2008
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	NL1380
NTR-old	NTR1440
Ander register	: 2007-002533-37 EudraCT nummer
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A