Bortezomib therapy combined with donor lymphocyte infusion in patients with relapsed Multiple Myeloma following allogeneic stem cell transplantation

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The combination of DLI with bortezomib given before and after the DLI improves the Graft versus Myeloma effect without effect on the Graft versus host disease

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

Samenvatting

ID

NL-OMON25090

Bron
NTR

Verkorte titel
DLI-Velcade studie

Aandoening

Multiple Myeloma/ Multiple Myeloom/ Morbus Kahler
Allogeneic stem cell transplantation/allogene stamceltransplantatie
Donor lymphocyte infusion/Donor lymfocyten infusie
Bortezomib

Ondersteuning

Primaire sponsor: UMC Utrecht, afdeling hematologie
Overige ondersteuning: geen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is response rate. The included patients will be analysed with analysis of the m-protein at entry, after bortezomib cycle 2, 4, 6, 8 and before administration of DLI or before cycle 4,6,8 if no more DLI is given. After each DLI before administration of bortezomib cycle 3, 5, 7 and in follow up every 2 months. Bone marrow examination
will be done on indication, for example confirmation of CR.

Toelichting onderzoek

Achtergrond van het onderzoek

Patients with multiple myeloma treated with an allogeneic SCT who are candidated for a DLI intervention because of relapse of their disease. These patients will first receive 2 cycli of bortezomib, then the DLI, and then again 2 cycli of bortezomib. The DLI and the bortezomin can be repeated, maximum is 3 DLI and 8 cycli of bortezomib

Doel van het onderzoek

The combination of DLI with bortezomib given before and after the DLI improves the Graft versus Myeloma effect without effect on the Graft versus host disease

Onderzoeksproduct en/of interventie

The intervention consists of a sequential approach over bortezomib cycli (2) with DLI. The bortezemib cycli are given before and 2 weeks after the DLI infusion. If the patient reaches a CR the treatment is
stopped. If a PR is reached the patient continues with bortezomib, maximum 8 cycli. In case of a minimal reaction the patient can receive a second and third DLI, combined with bortezemib. During the study blood and bone marrow sampling will determine the response rate. This is no
control group, comparison with historical data will be performed.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male or female and at least 18 years-of-age;
2. MM patients with any type of relapse or progressive disease following (non) myeloablative allo-SCT for which DLI is considered a treatment option (including patients previously participating in Hovon 54 or Hovon 65 studies);
3. Informed consent;
4. Haematological parameters; Hb > 4.0 mmol/L, leucocytes > 1.0¡Á109/L , thrombocytes > 25 ¡Á109/L, with or without transfusion

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Use of the immunosuppressive drugs cyclosporin, MMF, or corticosteroids;
2. Existing GvHD > grade A;
3. Any non-hematological toxicity CTC grade ¡Ý 3;
4. Neuropathy and/or neuropathic pain CTC grade ¡Ý 2;
5. Pregnancy;
6. History of allergic reaction to compounds containing boron or mannitol;
7. Uncontrolled or severe cardiovascular disease, including myocardial infarctiin within 6

months, NYHA class III of IV heart failure (appendix E), uncontrolled angina, clinically significant pericardial disease or cardiac amyloidosis;
8. Previous use of bortezomib is not an exclusion criterion, however patients refractory to bortezomib during previous treatments are excluded from this study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2007
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-04-2007
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	NL925
NTR-old	NTR949
Ander register	:
ISRCTN	ISRCTN53810679

Resultaten

Samenvatting resultaten

1. Lokhorst HM, Wu K, Verdonck LF et al. The occurrence of graft-versus-host disease is the major predictive factor for response to donor lymphocyte infusions in multiple myeloma. Blood 2004;103:4362-4364.
2. van de Donk NW, Kroger N, Hegenbart U et al. Remarkable activity of novel agents bortezomib and thalidomide in patients not responding to donor lymphocyte infusions following nonmyeloablative allogeneic stem cell transplantation in multiple myeloma. Blood 2006;107:3415-3416.
3. Kroger N, Shimoni A, Zagrivnaja M et al. Low-dose thalidomide and donor lymphocyte infusion as adoptive immunotherapy after allogeneic stem cell transplantation in patients with multiple myeloma. Blood 2004;104:3361-3363.
4.Sun K, Welniak LA, Panoskaltsis-Mortari A et al. Inhibition of acute graft-versus-host disease with retention of graft-versus-tumor effects by the proteasome inhibitor bortezomib. Proc.Natl.Acad.Sci.U.S.A 2004;101:8120-8125