

Bortezomib (Velcade®) therapy combined with Donor Lymphocyte Infusion in patients with relapsed multiple myeloma following allogeneic stem cell transplantation

Submission date 30/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/09/2007	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Acronym

DLI-Velcade® study

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

interventional, non-randomised, non-controlled, multicentre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multiple myeloma

Interventions

The intervention consists of a sequential approach over bortezomib cycli (2) with DLI. The bortezomib 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 bortezomib. 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.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bortezomib (Velcade®), Donor Lymphocyte Infusion

Primary outcome(s)

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.

Key secondary outcome(s)

Secondary outcomes are evaluated at the same time points as the primary outcome. Blood samples for experimental immunology are taken before:

1. First administration of bortezomib in cycle one
2. First DLI
3. First administration of bortezomib in cycle three
4. Second DLI
5. First administration of bortezomib in cycle five
6. Third DLI
7. First administration of bortezomib in cycle seven
8. Stopped treatment and/or occurring GvHD

Completion date

01/05/2009

Eligibility

Key inclusion criteria

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 $\times 10^9$ /L, thrombocytes > 25 $\times 10^9$ /L, with or without transfusion

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

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

Date of first enrolment

01/05/2007

Date of final enrolment

01/05/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Centre Utrecht

Utrecht

Netherlands

3508 GA

Sponsor information

Organisation

University Medical Centre Utrecht (UMCU) (The Netherlands)

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Centre Utrecht (UMCU) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration