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

Submission date
30/05/2007

Registration date
30/05/2007

Last Edited
21/09/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M.C. Minnema

Contact details
University Medical Centre Utrecht
Department of Haematology, B02.226
P.O. Box 85500
Utrecht
Netherlands
3508 GA
+31 (0)30 2507230
m.c.minnema@umcutrecht.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

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

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Multiple myeloma

Interventions
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.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Bortezomib (Velcade®), Donor Lymphocyte Infusion

Primary outcome measure
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.

Secondary outcome measures
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

Overall study start date
01/05/2007

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¡Á109/L , thrombocytes > 25 ¡Á109/L, with or without transfusion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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 ¡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.

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)

Sponsor details

Department of Haematology
P.O. Box 85500
Alkmaar
Netherlands
3508 GA

Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Utrecht (UMCU) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration