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

Published: 13-11-2006
Last updated: 20-05-2024

Primary objectives:Efficacy of bortezomib combined with DLI in patients with relapse myeloma following (non) myeloablative allo-SCT as measured by- response rate including percentage of complete remission according to EBMT criteria (appendix A)-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Plasma cell neoplasms
Study type	Interventional

Summary

ID

NL-OMON31757

Source
ToetsingOnline

Brief title
Bortezomib and DLI in relapsed myeloma

Condition

- Plasma cell neoplasms

Synonym
bone marrow cancer, plasmacel dyscrasia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Janssen-Cilag

Intervention

Keyword: DLI, Graft versus myeloma, Multiple myeloma, Novel agents

Outcome measures

Primary outcome

Myeloma response criteria and event free and overall survival (kaplan-meier)

Secondary outcome

Toxicity as determind by GvHD criteria and CTC

Study description

Background summary

Donor lymphocyte infusion is the standard of care for patients with a relapse following allogeneic stem cell transplantation, resulting in a response rate of 30-40% in myeloma. Velcade (Bortezomib) is registered for relapsed myeloma resulting in a response rate of 30-40%. We retrospectively found that combination of both therapies increased response rate dramatically (> 70%). It seems rational to combine both treatments in patients with relapsed myeloma following allogeneic stem cell transplantation and test this approach prospectively.

Study objective

Primary objectives:
Efficacy of bortezomib combined with DLI in patients with relapse myeloma following (non) myeloablative allo-SCT as measured by
- response rate including percentage of complete remission according to EBMT criteria (appendix A)
- Event free survival/EFS (i.e. time from registration to progression or death from any cause
whichever occurs first) and overall survival/OS.

Secondary objective

- toxicity including evaluation of GvHD and CTC grade toxicity (Appendix B and C)
- evaluation of immune modulating effects of combined treatment with DLI and bortezomib as measured by serial plasma samples

Study design

Prospective Phase II study

Intervention

Bortezomib followed by DLI, eventually followed by continuation of Bortezomib treatment and DLI

Study burden and risks

The most important side effect of DLI is acute and chronic GvHD which occurs in about 40 % of patients and will be severe in a small percentage of the patients (< 10%).
The most important side effect of Bortezomib is polyneuropathy which occurs in about 40 % of patients and when adequately monitored will not exceed > grade 1.

There are no indications from the retrospective study that side effects become more severe of more frequent when both therapies are combined.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Relapsed multiple myeloma following allogeneic stem cell transplantation

Exclusion criteria

Active Graft versus Host disease
Polyneuropathy > grade 1
use of immunosupresssive drugs with the exception of low dose prednisone orally or in ointment

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-06-2007
Enrollment:	20

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Velcade
Generic name:	Bortezomib
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	13-11-2006
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	10-04-2007
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-09-2007
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-03-2008
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-04-2008
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2006-005007-34-NL
CCMO	NL14315.041.06