Bortezomib in combination with continuous low-dose oral cyclophosphamide and dexamethason followed by maintenance in primary refractory or relapsed bortezomib naïve multiple myeloma patients

Published: 10-09-2008
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Evaluation of the safety and efficacy of bortezomib combined with cyclophosphamide and dexamethasone for induction and maintenance therapy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON38293

Source
ToetsingOnline

Brief title
Relapse myeloma; cyclofosfamide; bortezomib; maintenance.

Condition

- Haematological disorders NEC

Synonym
Multiple myeloma; M. Kahler.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Janssen Cilag gedeeltelijk

Intervention

Keyword: Relapse myeloma, treatment.

Outcome measures

Primary outcome

Toxicity and efficacy of the combination of Bortezomib, Cyclofosfamide and

Dexametason during induction and maintenance therapy.

Secondary outcome

Survival

Study description

Background summary

To improve the treatment efficacy in patients with a relapse MM.

Study objective

Evaluation of the safety and efficacy of bortezomib combined with cyclophosphamide and dexamethasone for induction and maintenance therapy.

Study design

Prospective multi-centre study.

Intervention

- Tripple therapy with Cyclofosfamide, Dexametason and Bortezomib during induction phase.
- Cyclofosfamide and Bortezomib during maintenance therapy.

Study burden and risks

- Increased bone marrow toxicity.
- i.v.or s.c. injection of Bortezomib during maintenance therapy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age >= 18 years
Stage II-III Multiple Myeloma
Relapse or primary refractory disease after initial chemotherapy
WHO performance status 0 - 2
Life expectancy of at least 6 weeks
ANC (absolute neutrophil count) >= 1.0x109/l
(or >= 0.5x109/l, if due to bone marrow infiltration by malignancy)
Platelet count >= 75x109/l

(or >= 50x109/l, if due to bone marrow infiltration by malignancy)
Written informed consent (present in patient*s file)
Patient is able and willing to use adequate contraception during therapy and for at least 1 month after study;Patient has the ability to understand the requirements of the study

Exclusion criteria

Previous treatment with bortezomib
Urine production < 1.5 l/24h
Pre-existent polyneuropathy (grade 2 or higher, according to CTCAE 3.0)
Pregnancy or positive pregnancy tests during study and for 1 month after final dose of thalidomide
History of active malignancy during the past 5 years (with the exception of basal carcinoma of the skin)
Active uncontrolled infections
Additional uncontrolled serious medical or psychiatric illness

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	73
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Velcade

Generic name:	Bortezomib
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	10-09-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-12-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-04-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2008-004822-17-NL
CCMO	NL24138.042.08