Phase II Study of Combination Bortezomib, Dexamethasone, and Rituximab in previously untreated Patients with Waldenstrom*s Macroglobulinemia: A multicenter Trial of the European Myeloma Network

Published: 11-12-2006
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The primary objective of this study is:To determine the response rate [the combined complete response (CR) + partial response (PR) + minimal response (MR)] following treatment with BDR in patients with previously untreated WM.Secondary objectives...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Haematopoietic neoplasms (excl leukaemias and lymphomas)
Study type	Interventional

Summary

ID

NL-OMON30654

Source
ToetsingOnline

Brief title
Combination BDR in Waldenstrom*s Macroglobulinemia

Condition

- Haematopoietic neoplasms (excl leukaemias and lymphomas)

Synonym
immunocytoma, lymphoplasmacytic lymphoma, Waldenstrom□s Macroglobulinemia

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,European Myeloma Network

Intervention

Keyword: Bortezomib, Dexamethasone, Rituximab, Waldenstrom□s Macroglobulinemia

Outcome measures

Primary outcome

Primary efficity parameters are the lab. results in comparison with the

baseline result.

Secondary outcome

Number of adverse events and side effects.

Study description

Background summary

Waldenstrom's macroglobulinemia (WM) is a distinct B-cell lymphoproliferative disorder characterized primarily by bone marrow infiltration with lymphoplasmacytic cells, along with demonstration of an IgM monoclonal gammopathy
Despite continuing advances in the therapy of WM, the disease remains incurable with a median survival of 5 to 8 years.

Study objective

The primary objective of this study is:
To determine the response rate [the combined complete response (CR) + partial response (PR) + minimal response (MR)] following treatment with BDR in patients with previously untreated WM.
Secondary objectives are:
To determine time to progression following treatment with BDR

To assess the safety and tolerability of BDR in patients with WM.

Study design

Screening, treatment and follow up fase. Treatment consists of 5 cycli of 35 days. Medications is given intravenously. Follow up visit outdoor patient clinic every 3 months for 2 years after which visits every 6-12 months.

Intervention

n.a.

Study burden and risks

The side effect of medication used is known, however the side effects caused by this combination of medicine are not known.

Contacts

Public
Academisch Medisch Centrum

Centrumlocatie, 's Gravendijkwal 230
3015 CE Rotterdam
NL
Scientific
Academisch Medisch Centrum

Centrumlocatie, 's Gravendijkwal 230
3015 CE Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Clinicopathological diagnosis of Waldenstrom*s macroglobulinemia as defined by consensus panel one of the Second International Workshop on Waldenstrom*s macroglobulinemia. All patients with the diagnosis of WM will be evaluable for response according to the response criteria.
No prior systemic treatment for WM. Prior plasmapheresis to control hyperviscosity, is allowed.

Exclusion criteria

Prior systemic treatment with WM (plasmapheresis is allowed)
Myocardial infarction within 6 months prior to enrollment or has New York Hospital Association (NYHA) Class III or IV heart failure, uncontrolled angina, severe uncontrolled ventricular arrhythmias, or electrocardiographic evidence of acute ischemia or active conduction system abnormalities. Prior to study entry, any ECG abnormality at Screening has to be documented by the investigator as not medically relevant.
Patient has hypersensitivity to dexamethasone, bortezomib, boron or mannitol.
Serious medical or psychiatric illness likely to interfere with participation in this clinical study.
Cardiac amyloidosis.
Peripheral neuropathy or neuropathic pain grade 2 or higher as defined by NCI CTCAE version 3.

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):	01-03-2007
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Decadron
Generic name:	Dexamethasone
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Mabthera
Generic name:	Rituximab
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Velcade
Generic name:	Bortezomib
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	11-12-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	15-02-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2006-003563-31-NL
CCMO	NL14911.078.06