Bortezomib maintenance therapy in newly diagnosed patients with mantle cell lymphoma, responsive on rituximab combined with CHOP and high dose Ara-C and after BEAM with auto PSCT rescue.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24708

Source
Nationaal Trial Register

Brief title
HOVON 75 MCL

Health condition

MCL (WHO classification)
Ann Arbor stage II ¨C IV
CD20 positive

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
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Source(s) of monetary or material Support: HOVON receives unrestricted grants and/or financial support from Amgen, Johnson&Johnson-Orthobiotech, Roche and Novartis for the execution of investigator sponsored trials. In addition HOVON is supported by the Dutch Cancer Society.

Intervention

Outcome measures

Primary outcome

Event free survival (EFS).

Secondary outcome

1. Residual disease (quality of remission) as measured with FDG-PET, flow cytometry and molecular studies;

2. Toxicity of bortezomib maintenance therapy after high dose treatment;

3. Overall survival.

Study description

Background summary

Study phase: II

Study objective:

Primary objective:To study the efficacy and toxicity of bortezomib maintenance after induction with HD Ara-C and stem cell transplantation.

Secondary objective:To study the value of FDG-PET, flow cytometry and IGVH–PCR for defining the quality of remission after induction with high dose chemotherapy and Rituximab, after auto PSCT and during maintenance treatment with bortezomib, in comparison to conventional definitions.

Patient population:
Patients with newly diagnosed mantle cell lymphoma who reached PR or CR after chemotherapy combined with rituximab and high dose treatment followed by autologous stem cell transplantation.

Study design:
Prospective, multicenter, phase II.

Duration of treatment:
Expected duration of induction, intensification and BEAM with Auto PSCT is 7 months. Maintenance therapy with bortezomib will be given for 2 years.

Study objective

The objective of this phase II study is to determine whether there is an indication that bortezomib maintenance might result in a better event free survival.

Study design

1. Event Free Survival: Hazard ratio and difference in 2 year EFS with 95% confidence intervals;

2. Overall Survival: Hazard ratio and difference in 2 year OS with 95% confidence intervals;

3. Development of quantifiable residual disease, as assessed by FDG-PET, flow cytometry and molecular studies during bortezomib maintenance in comparison without further treatment.

Intervention

All registered patients will be treated with three courses of R-CHOP followed by two courses of HD Ara-C plus Rituximab. Patients with SD or PD (conventional criteria) after the second HD Ara-C course will go off study. Patients in CR or PR will continue with an autologous stem cell transplantation after BEAM conditioning. After this, patients will be randomized for treatment with bortezomib maintenance therapy or no further treatment, unless there is progression or relapse.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with histologically and immunologically proven diagnosis of MCL (WHO classification);

2. Ann Arbor stage II ¨C IV;

3. CD20 positive;

4. Age 18 - 65 years (inclusive);

5. WHO performance ¡Ü 2;

6. Measurable disease (also patients with isolated bone marrow disease are accepted) (appendix B);

7. Written informed consent.

Exclusion criteria

1. Renal failure (creatinine clearance < 50 ml/min);

2. Known hypersensitivity to murine antibodies, boron or mannitol;

3. Any other organ dysfunction or failure that may present a risk to the patient during any phase of protocol treatment;

4. Presence of CNS involvement by NHL;

5. Known HIV and hepatitis B or C seropositivity;

6. Pregnancy or lactation;

7. Prior treatment with chemotherapy, radiotherapy or immunotherapy for this lymphoma,

except local radiotherapy in case of (potential) organ dysfunction by localized lymphoma mass or infiltration;

8. Other active malignancy (less than 5 years in complete remission) except skin (non-melanoma) or cervix carcinoma stage 1;

9. Active systemic infection requiring treatment;

10. Peripheral neuropathy or neuropathic pain Grade 2 or higher as defined by NCI CTCAE version 3;

11. Uncontrolled or severe cardiovascular disease, including MI within 6 months of enrolment, New York Heart Association (NYHA) Class III or IV heart failure, uncontrolled angina, clinically significant pericardial disease, or cardiac amyloidosis;

12. Serious medical condition (such as severe hepatic impairment, pericardial disease, acute diffuse pulmonary disease, systemic infections etc) or psychiatric illness likely to interfere with participation in this clinical study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2007
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-04-2009
Application type:	First submission

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
NTR-new	NL1671
NTR-old	NTR1772
Other	METC Erasmus MC : 2006-086
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A