Feasibility and Efficacy of dose adjusted Melphalan ¨C Prednisone ¨C Bortezomib (MPV) in elderly patients >= 75 years of age with newly diagnosed Multiple Myeloma; a non-randomised phase II study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21015

Source
NTR

Brief title
HOVON 123 MM

Health condition

Multiple Myeloma; Bortezomib; Kahler

Sponsors and support

Primary sponsor: Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON)
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Source(s) of monetary or material Support: HOVON; Janssen Pharmaceuticals; Koningin Wilhelmina Fonds (KWF)

Intervention

Outcome measures

Primary outcome

The main endpoint for this trial is the discontinuation rate, i.e. the proportion of patients who cannot complete all 9 MPV cycles according to protocol.

Secondary outcome

Safety and toxicity as defined by type, frequency and severity of adverse events as defined by the National Cancer Institute (NCI) Common Terminology Criteria (CTC), version 4.0
Overall response rate where response is defined as sCR, CR, VGPR or PR
Time to response
Progression free survival , defined as time from registration to progression, relapse or death from any cause whichever occurs first
Overall survival, measured from time of registration to death. Patients still alive or lost to follow up are censored at the date they were last known to be alive (date last contact)
Relative dose intensity and cumulative dose intensity of Melphalan, Prednisone and Bortezomib
Predictive value of geriatric assessments
Quality of life as defined by the EORTC QLQ-C30 and MY-20 definitions
Association of biomarkers for biological age with toxicity and feasibility of the treatment
Associations with toxicity and with feasibility of the treatment regimen of polymorphism of genes involved in drug metabolism and related with bortezomib-induced PNP
Association of risk factors and myeloma gene expression profiles with prognosis
The incidence of bone remodeling during treatment and the association with response to therapy
Cost effectiveness as defined by the EQ-5D-5L and the involved costs

Study description

Background summary

Study phase: phase II

Study design: Prospective, multicenter
Duration of treatment: 9 months

Study objective:
To assess discontinuation rate, i.e. the proportion of patients who cannot complete all 9 MPV cycles according to protocol

To assess relative dose intensity and cumulative dose intensity of MP- Bortezomib

To assess predictive value of geriatric assessments and the patients quality of life

Study objective

This study aims to assess the feasibility of a dose-adjusted MPV scheme in patients >= 75 years of age and to assess the value of geriatric assessments to predict both feasibility and efficacy.

Study design

At entry: before start of treatment
During induction therapy after 1, 3, 5 ,7 and 9 cycles

Intervention

The patients receive nine courses MPV treatment (= Melphalan, Prednisone, Bortezomib). (Bortezomib is the generic name Velcade). Each course lasts five weeks. The total duration of the treatment is 11 months (9 cycles of 4 weeks), then at follow up to 5 years. Progression or severe toxicity, treatment stops and the patient in follow-up. The first visit takes ~ 2 hours, then it takes ~ 1 hour hospital visit. Response term evaluation after treatment, there is 1, 3, 5, 7 and 9.

The study of blood and bone marrow decreased but this is done during regular withdrawals so that the patient is not pricked extra. Additionally in this study are five quality of life questionnaires completed at various times. A geriatric assessment is also taken that extra time consuming and can be for the patient. Incriminating Finally, a huisbiopt decreased.

Contacts

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Eligibility criteria

Inclusion criteria

- Previously untreated patients with a confirmed diagnosis of symptomatic multiple myelomaaccording to IMWG criteria (see appendix A)
- Age ≥ 75 years
- WHO performance status 0-3, WHO 4 performance status is allowed when related to MM (see appendix E)
- Measurable disease as defined by the presence of M-protein in serum or urine and/or abnormal free light chain (FLC) ratio with involved FLC (see appendix A for definitions). (If plasmacytoma is the only measurable parameter, the patient is not allowed to be included in the study, because of difficult response evaluation).
- Patient gives consent for extra bone marrow, blood and skin biopsy sampling
- Written informed consent

Exclusion criteria

- Non-secretory MM
- Systemic Amyloid Light-chain (AL) amyloidosis
- Polyneuropathy, grade 1 with pain or grade ≥ 2
- Severe cardiac dysfunction (NYHA classification IV, appendix F)
- Severe pulmonary dysfunction defined as breathlessness at rest
- Significant hepatic dysfunction (total bilirubin ≥ 30 ¦Ìmol/l or transaminases ≥ 3 times normal level), unless related to MM
- Renal insufficiency requiring dialysis
- Patients with active, uncontrolled infections
- Pre-treatment with cytostatic drug, immunomodulatory drugs (IMiDs) or proteasome inhibitors. Radiotherapy or a short course of steroids (e.g. 4 day treatment of dexamethasone 40 mg/day or equivalent) are allowed
- Patients known to be Human Immunodeficiency Virus (HIV)-positive
- Active malignancy other than MM requiring treatment or a malignancy that has been treated with chemotherapy currently affecting bone marrow capacity
- Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and follow-up schedule

- Patients with plasma cell leukemia

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2013
Enrollment:	240
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	29-10-2013
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	NL4099
NTR-old	NTR4244
Other	EudraCT nummer : 2013-000320-33
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A