High dose simvastatin combined with standard chemotherapy in patients with refractory Multiple Myeloma: a phase II study.

No registrations found.

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

Summary

ID

NL-OMON20029

Source
NTR

Brief title
High dose simvastatin combined with standard chemotherapy in patients with refractory Multiple Myeloma: a phase II study

Health condition

multiple myeloma

Sponsors and support

Primary sponsor: The study is conducted on the department of hematology in het University Medical Center Utrecht. The study is approved by the Medical Ethical Board of this same hospital.
Source(s) of monetary or material Support: Dutch Cancer Society
International myeloma foundation

Intervention

Outcome measures

Primary outcome

The primary endpoint is response as defined by the EBMT criteria. This group of extensively pre-treated patients are multiresistent and we defined -based in literature- a respose of 10-30% as reasonable.

Secondary outcome

We recently performed a phase I study to define the maximum tolerated dose (MTD) and dose-limiting toxicity(DLT) (published in Haematologica 2006; 91:542-545) of high dose simvastatin, combined with VAD. Secondary outcome is to confirm the faesibility as shown in this phase I trial.

Study description

Background summary

In a prospective fase II study, we evaluated the combination of high dose simvastatin and VAD chemotherapy in patients with refractory or relapsed multiple myeloma. Although treatment was feasible with mild side effects, we found that after treatment of 12 patients, only 1 patient achieved a partial response. According to our predefined criteria this was insufficient to continue the study.

Study objective

Simvastatin (an HMG-CoA reductase inhibitor) induces apoptosis in vitro and sensitizes the myeloma cell to chemotherapy. This is the first clinical trial to test if in vivo there is the same sensitization in relapse or refractory multiple myeloma.

Study design

N/A

Intervention

Treatment of relapsed/ refractory multiple myeloma patients with high dose statins, combined with chemotherapy. We treat multiple myeloma patients with 15 mg/kg simvastatin Day 0-7 followed by VAD day 7-11 (Vincristin, adriamycin, dexamethasone)chemotherapy in a scheme as used in HOVON trials (eg HOVON 65). On day 29 a new cycle is started. Patients are treated with 3 cycles. An additional cycle can be given in case of response (MR, PR ,CR).

In case of progressive disease during treatment, the therapy is ended.

Contacts

Public
University Medical Center Utrecht
Dept of Hematology
P.O.Box 85500
E. Spek, van der
Heidelberglaan 100
Utrecht 3508 AB
The Netherlands
+31-30-2507655
Scientific
University Medical Center Utrecht
Dept of Hematology
P.O.Box 85500
E. Spek, van der
Heidelberglaan 100
Utrecht 3508 AB
The Netherlands
+31-30-2507655

Eligibility criteria

Inclusion criteria

1. Multiple myeloma patients;

2. At least two cycles of chemotherapy with adriamycin and dexamethasone;

3. age < 75 y.

Exclusion criteria

1. Inadequate hepatic and renal function.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	03-05-2005
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-05-2007
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	NL962

Register	ID
NTR-old	NTR988
Other	: 04/239
ISRCTN	ISRCTN85384018

Study results