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

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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.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20029

Bron
NTR

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

Aandoening

multiple myeloma

Ondersteuning

Primaire 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.
Overige ondersteuning: Dutch Cancer Society
International myeloma foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Multiple myeloma patients;

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

3. age < 75 y.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Inadequate hepatic and renal function.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	03-05-2005
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-05-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL962
NTR-old	NTR988
Ander register	: 04/239
ISRCTN	ISRCTN85384018

Resultaten