RNA-DC vaccination in multiple myeloma.

No registrations found.

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

Summary

ID

NL-OMON27113

Source
Nationaal Trial Register

Brief title
N/A

Health condition

1. DC vaccination;

2. Multiple myeloma;

3. Immune therapy minimal residual disease.

-DC vaccinatie
-Multiple myeloma
-Immunotherapie
-Minimale restziekte

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Center, Dept. of Hematology

Universitair Medisch Centrum Sint Radboud, Afd. Hematologie
Source(s) of monetary or material Support: 1. Dutch Cancer Society (KWF)
2. Stichting Nijmeegs Offensief Tegen Kanker

Intervention

Outcome measures

Primary outcome

In vivo immune response to the tumor associated antigen epitopes in at least 3 out of 10 patients will be considered as a positive result. No response to any of the antigens will be considered a negative result.

Secondary outcome

Secondary end-points are clinical responses and decrease of minimal residual disease by molecular monitoring (ASO-PCR).

Study description

Background summary

Patients with multiple myeloma (MM) are treated with intensive chemotherapy, which frequently induces a status of minimal residual disease, but finally all patients will relapse. Allogeneic transplantation as a form of immunotherapy may prolong remission and even cures the disease, but only in a minority of the patients and with significant toxicity. In a pilot study we vaccinated MM patients with mature DC loaded with idiotype as an alternative form of immunotherapy. We showed the feasibility and a very limited toxicity, but the idiotype antigen appeared only weakly immunogenic. In this study we will vaccinate with 3 different proteins, Mage-3, Survivin and BCMA, all shown to be highly expressed on malignant plasma cells. Autologous mature DC, electroporated with tumor associated antigen messenger RNA, will be used to present the antigens to the immune system.

Study objective

The primary goal is to show the capability of monocyte-derived DC after RNA electroporation for multiple antigens to induce an immune response. The secondary objective is to show clinical response.

Study design

Patients will be treated by 4 DC vaccinations at 2 weeks interval. In case of response the procedure can be repeated to boost the immune response.

For follow-up we will collect blood (at day 14, 28, 42, 56 and 70 after DC vaccination) and bone marrow aspirates (at 3, 6, 12 months after chemotherapy during 1st year).

Intervention

Patients monocytes will collected by apheresis. Patients will be vaccinated intravenous and intradermal at 4 occasions with 2 weeks interval. Monitoring will be done for toxicity, immune response and minimal residual disease.

Contacts

Public
Universitair Medisch Centrum Sint Radboud
Datacentrum Hematologie
Intern adres 476
Geert Grooteplein zuid 10
O. Huber
Universitair Medisch Centrum Sint Radboud
Datacentrum Hematologie
Intern adres 476
Geert Grooteplein zuid 10
Nijmegen 6525 GA
The Netherlands
024 3614794
Scientific
Universitair Medisch Centrum Sint Radboud
Datacentrum Hematologie
Intern adres 476
Geert Grooteplein zuid 10
O. Huber
Universitair Medisch Centrum Sint Radboud
Datacentrum Hematologie
Intern adres 476
Geert Grooteplein zuid 10
Nijmegen 6525 GA
The Netherlands
024 3614794

Eligibility criteria

Inclusion criteria

1. Age 18-70 years;

2. Patients with stage II and III MM;

3. Complete remission (CR) or partial response (PR) following intensive therapy, including high dose melphalan and autologous stem cell transplantation;

4. Measurable minimal residual disease by M-component (complete of light chain) or molecular disease by BM Ig heavy chain rearrangement (ASO-PCR);

5. Myeloma cells expressing 2-3 of the 3 TAA used for vaccination, each in >20% of CD138+CD38++ plasma cells;

6. Interval of >6 months after completion of intensive chemotherapy;

7. Life expectancy >6 months;

8. Expected adequacy for follow-up including bone marrow evaluation;

9. Written Informed consent.

Exclusion criteria

1. Progressive disease (increase in M-component of >25% in the last 3 months);

2. Patients on immunosuppressive drugs;

3. Patients with active infections (viral, bacterial or fungal) that requires specific therapy;

4. Acute therapy must have been completed within 14 days prior to study treatment;

5. Patients with known allergy to shell fish (contains KLH);

6. Patients with pregnancy or lactation;

7. WHO performance status 4;

8. Allogeneic stem cell transplantation.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2007
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-10-2007
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	NL1053
NTR-old	NTR1086
Other	Trialcoördinatie Data Centrum van de afdeling Hematologie : PMM17
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A