RNA-DC vaccination in multiple myeloma.

Gepubliceerd: 15-10-2007 Laatst bijgewerkt: 18-08-2022

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.

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

Samenvatting

ID

NL-OMON27113

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

1. DC vaccination;

2. Multiple myeloma;

3. Immune therapy minimal residual disease.

-DC vaccinatie
-Multiple myeloma
-Immunotherapie
-Minimale restziekte

Ondersteuning

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

Universitair Medisch Centrum Sint Radboud, Afd. Hematologie
Overige ondersteuning: 1. Dutch Cancer Society (KWF)
2. Stichting Nijmeegs Offensief Tegen Kanker

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2007
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-10-2007
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	NL1053

Register	ID
NTR-old	NTR1086
Ander register	Trialcoördinatie Data Centrum van de afdeling Hematologie : PMM17
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A