Dendritic cell vaccination in multiple myeloma.

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After non-myeloablative allogeneic SCT the hematopoiesis is from donor origin (100% donor chimerisme) in almost all cases. The origin of DCs is important in presenting minor antigens to donor T-cells. Autologous or host DCs are capable to directly…

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

Samenvatting

ID

NL-OMON26115

Bron
NTR

Verkorte titel
APC study

Aandoening

Multiple Myeloma

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: KWF

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toxicity.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

After non-myeloablative allogeneic SCT the hematopoiesis is from donor origin (100% donor chimerisme) in almost all cases. The origin of DCs is important in presenting minor antigens to donor T-cells. Autologous or host DCs are capable to directly present minor antigens, while donor DCs can present minor antigens only by cross presentation, which implies active uptake of recipient antigens. As such, host DCs are much better capable to induce graft versus myeloma and graft versus host disease. This concept was confirmed in animal studies and is suggested to be important in humans.

Primary objective:

To evaluate the feasibility of combined DC vaccination and DLI, in the induction of graft-versus-host disease.

Secondary objective:

1. To evaluate the efficacy of combined DC vaccination and DLI to induce a graft-versus-myeloma response;

2. To evaluate the effect of combined DC vaccination and DLI on the immune status of the recipient in correlation with toxicity and response.

Onderzoeksopzet

Dendritic cell vaccination is given at 0, 2 and 4 weeks.

Onderzoeksproduct en/of interventie

Administration of autologeous dendritic cells combined with donor T-cells.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Multiple myeloma patients with relapsed disease after a non- myeloablative allo-SCT, who have not responded 3 months after a first course of DLI with 1 x 107 T cells/kg body weight;
OR

2. Multiple patients who have received a non myeloablative Allo-SCT from a sibling or MUD donor for relapsed disease after a previous autologous SCT and who have not responded 3 months after a first course of pre-emptive DLI with 1 x 107 T cells/kg (1 x 106 T cells/kg, in case of MUD) cells/kg body weight;
AND

3. Age 18-70 years;

4. Absence of acute GvHD > grade A;

5. Absence of extensive chronic GvHD;

6. WHO performance 0-2;

7. Absence of severe cardiac hepatic, renal, metabolic disease;

8. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Not further specified.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	11-08-2006
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-06-2009
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	NL1762
NTR-old	NTR1872
Ander register	05/263 : UMCU METC
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A