Dendritic cell vaccination in multiple myeloma.

No registrations found.

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

Summary

ID

NL-OMON26115

Source
NTR

Brief title
APC study

Health condition

Multiple Myeloma

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: KWF

Intervention

Outcome measures

Primary outcome

Toxicity.

Secondary outcome

Efficacy.

Study description

Background summary

N/A

Study objective

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.

Study design

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

Intervention

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

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

Not further specified.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-08-2006
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

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

Study results

Summary results
N/A