Infusion of host dendritic cells to improve the graft versus myeloma effect of donor lymphocyte infusion. A phase I/II study.

No registrations found.

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

Summary

ID

NL-OMON28206

Source
NTR

Brief title
APC study

Health condition

patients with multiple myeloma who have received an autologeous and allogeneic SCT

Sponsors and support

Source(s) of monetary or material Support: Senior award MMRF

Intervention

Outcome measures

Primary outcome

Feasibility of combined DC vaccination and DLI in the induction of graft versus host disease.

Secondary outcome

1. Efficacy of combined DC vaccination and DLI to induce a graft versus myeloma response;
2. Effect of combination on the immune status of the recipient in correlation with toxicity and response.

Study description

Background summary

In this study we seek to enhance the positive effects of immunotherapy in multiple myeloma patients. patients with relapse MM who do no respons to their first course of DLI can participate. The second course of DLI (same dose) will be combined with infusion of autologeous dendritic cells, manufactured from stem cells. This infusion will be done 3 times. Primary outcome is the safety of this approach, secondary the efficacy.

Study objective

After allogeneic stem cell transplantation (SCT) the hematopoiesis is from donor origin. Laboratory and animal studies suggests that de dendritic cells of host origin are important in inducing graft versus myeloma effect and graft versus host disease (GvHD). We hypothesize that infusion of host dendritic cells in patients with multiple myeloma after allogeneic SCT together with donor lymphocyte infusion (DLI) can induce a graft versus myeloma effect.

Intervention

1. Infusion of DLI together with infusion of APC/dendritic cells;
2. SC injection of APC +/- KLH;
3. APC infusion and injection is repeated 2 times with a 2-week interval;
4. DTH test skin in week 6.

Contacts

Public
University Medical Center Utrecht (UMCU),
Department of Hematology (B02.226),
P.O. Box 85500
H.M. Lokhorst
Utrecht 3508 GA
The Netherlands
+31 (0)88 7557230

Scientific
University Medical Center Utrecht (UMCU),
Department of Hematology (B02.226),
P.O. Box 85500
H.M. Lokhorst
Utrecht 3508 GA
The Netherlands
+31 (0)88 7557230

Eligibility criteria

Inclusion criteria

1. Relapse of multiple myeloma;
2. No response of first course of DLI;
3. age 18-70;
4. WHO PS 0-2;
5. Written informed consent.

Exclusion criteria

1. Acute GvHD > grade A;
2. Extensive chonic GvHD;
3. Cardiac, hepatic, renal or uncontrolled metabolic disease.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-03-2006
Enrollment:	5
Type:	Anticipated

Ethics review

Positive opinion Date:	16-02-2006
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	NL569
NTR-old	NTR625
Other	: N/A
ISRCTN	NO ISRCTN (not randomized)

Study results

Summary results

Lokhorst HM, DLI for relapsed MM after allogeneic SCT: predictive factors for response and long-term outcome. JCO 00;18:303-37
Lokhorst HM. the occurrence of GvHD is the major predictive factor for response to DLI in MM. Blood 04,103:4362-64

Mapara MY. DLI mediate superior graft vs leukemia effcets in mixed compared to fully allogeneic chimeras: a critical role for host antigen presenting cells. Blood 02,100:1903-09