# 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**
Nationaal Trial Register

**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.

# Contacts

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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