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Prophylactic infusion of CD4 positive donor lymphocytes early after T-cell depleted stem cell transplantation

Submission date 31/08/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/06/2008	**Overall study status** Completed	
Last Edited 14/11/2013	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof J H F Falkenburg

Contact details
Leiden University Medical Centre
Albunisdreef 2
Leiden
Netherlands
2333 ZA
+31 (0)71 526 2271
J.H.F.Falkenburg@lumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LUMC 2007-01

Study information

Scientific Title

Study objectives
Infusion of CD4 positive donor lymphocytes after T-cell depleted stem cell transplantation will increase immune reconstitution.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Committee on Research involving Human Subjects, Netherlands (CCMO). Date of approval: 27/05/2008

Study design
Phase II, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Haematological malignancy

Interventions
Infusion with CD4 positive donor lymphocytes vs standard care.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Immune reconstitution at 6 months.

Secondary outcome measures
1. Chimerism and disease status as measured by minimal residual disease at 6 months
2. Incidence of viral infections between 3 and 6 months

Overall study start date
01/07/2008

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Both males and females
2. Age from 18 to 70 years
3. Patients with acute myeloid leukaemia (AML), myelodysplasia (MDS), acute lymphocytic leukaemia (ALL), chronic myeloid leukaemia (CML) in accelerated phase or blastic transformation, chronic lymphocytic leukaemia (CLL), multiple myeloma (MM) or aggressive lymphoma, who received an allogeneic stem cell transplantation.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Systemic immunosuppressive treatment
2. Progressive Graft Versus Host Disease (GVHD)
3. GVHD of the skin greater than grade 2
4. Progressive disease needing cytoreductive treatment

Date of first enrolment
01/07/2008

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre
Leiden
Netherlands
2333 ZA

Sponsor information

Organisation
Leiden University Medical Centre (Netherlands)

Sponsor details
Albunisdreef 2
Leiden
Netherlands
2333 ZA

Sponsor type
Hospital/treatment centre

Website
http://www.lumc.nl

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leiden University Medical Centre (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/09/2013		Yes	No