

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/06/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/11/2013	Condition category Cancer	<input type="checkbox"/> Individual participant data

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