

ReACH: Phase II study of reduced intensity sibling allogeneic transplantation for relapsed, chemosensitive, PET-positive Hodgkin lymphoma

EudraCT 2008-004955-31

REC Ref: 09/H0804/73

End of trial Summary

The ReACH trial opened to recruitment on 19 March 2010, and closed to recruitment early due to poor recruitment on 21 June 2012. Three patients were recruited into the trial. Patients who would have been eligible for ReACH can now be treated on its sister trial, PAIReD. The final patient was registered into the trial in December 2011 and transplanted in early February 2012. All patients were at least 4 months post transplant when the trial ended. Patients are now being followed up locally as per standard practice, and no long term follow up data is being collected.

Due to the small number of patients recruited into ReACH, no reliable results can arise from the trial.

Recruitment

12 sites were opened to recruitment

2 sites entered patients into the trial.

Site	No. recruited
University College Hospital, London	1
Christie Hospital, Manchester	2
TOTAL RECRUITMENT	3

Treatment compliance

Treatment	Day
Fludarabine 30mg/m ²	-7 to -3
Melphalan 140mg/m ²	-2
Alemtuzumab 30mg	-1
Peripheral blood stem cells or bone marrow	0

All 3 patients received reduced intensity fludarabine-melphalan-campath conditioned transplants, receiving stem cells from a matched sibling donor as per the trial protocol.

Pharmacovigilance

Graft-versus-host disease

1 patient developed acute graft-versus-host disease (onset 6.5 months post-transplant)

Infection

All 3 patients developed infections post-transplant:

- 1 x pneumonia (fatal)
- 2 x neutropenic sepsis
- 1 x CMV infection

SAE summary

Event type	No. reported
Total number of SAEs reported	1
Total number of SARs reported	1
Total number of SUSARs reported	0

Patient outcomes

Patient No	Date of transplant	Date of relapse	Date of death	If alive, date last seen
REA01	16.09.2010	N/A	17.10.2010 *	N/A
REA02	20.10.2010	N/A	N/A	17.08.2012
REA03	02.02.2012	N/A	N/A	13.11.2012

* Cause of death – pneumonia, expected complication of transplant

Report by Pip Patrick, Senior Trial Coordinator

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