

London-Dulwich NRES Committee  
 Health Research Authority  
 National Research Ethics Service  
 Skipton House  
 Ground Floor  
 80 London Road  
 London  
 SE1 6LH

King's College Hospital  
 Denmark Hill  
 London SE5 9RS

Tel: 020 3299 9000  
 Fax: 020 3299 3445  
 www.kch.nhs.uk

10<sup>th</sup> October 2013

To whom it may concern:

**END OF TRIAL SUMMARY / REPORT:**

<b>Full title of study:</b>	Single Centre Phase II Pilot study of unrelated cord blood transplantation in patients with poor risk haematological malignancies
<b>EudraCT number:</b>	2007-001657-26
<b>Research sponsor:</b>	King's College Hospital NHS Foundation Trust & King's College London
<b>Name of Chief Investigator:</b>	Prof Antonio Pagliuca
<b>Name of main REC:</b>	London – Dulwich (South East London REC 3)
<b>Main REC reference number:</b>	07/H0808/193
<b>Local R&amp;D Approval (open for recruitment)</b>	22 <sup>nd</sup> September 2009

**Contact details for person making this notification:**

<b>Name:</b>	Mr Warren Leung BSc
<b>Address:</b>	King's College Hospital NHS Foundation Trust Denmark Hill London, SE5 9RS
<b>Telephone:</b>	020 3299 5062
<b>Fax:</b>	020 3299 1032
<b>Email:</b>	<a href="mailto:warren.leung@nhs.net">warren.leung@nhs.net</a>
<b>Date of this notification:</b>	30 <sup>th</sup> September 2013

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Denmark Hill  
London SE5 9RS

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Fax: 020 3299 3445

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**Subject(s) Recruited:**

Subject Number	Date Consent Signed	Date started treatment	Date of Withdrawal	Reason for Withdrawal
001	01/09/2010	16/09/2010	19/12/2010	Death

**SAE, SAR or SUSAR report:**

Subject Number	SAE, SAR or SUSAR	Description of Event/Reaction	Criteria of SAE, SAR or SUSAR	Related to IMP(s)	Outcome
001	SAE	Chest Tightness - dizziness	Life threatening	Unlikely	Recovered

**NOTE:** Death was not reported as an SAE as Death was deemed to be due to disease progression which according to the protocol does not require reporting as an SAE.

**Objectives & Outcome:**

Objective	Outcome
To determine the safety and feasibility of unrelated double and single cord blood transplantation in patients with haematological malignancies using reduced-intensity or myeloablative conditioning regimens	The above study objective was unfortunately not met. This was primarily due to difficulties in recruiting, thus the trial had been closed. Only one patient had been recruited to the study, and closing of the trial was purely due to recruitment issues and not due to safety concerns.

**Further information:**

Due to only one patient being recruited and thus a single set of data. No database was or will be created, nor will any analysis of the data take place. Also no publication of the data analysis has or will take place.

Yours faithfully



Professor Antonio Pagliuca  
Clinical Director in Haematological Medicine  
Kings College Hospital NHS Foundation Trust