Clinical trial TC07.

Title	Allogeneic hematopoietic cell transplantation from HLA-matched donors after reduced-intensity conditioning : a phase II randomized study comparing 2 GVHD prophylaxis regimen
Summary	**Objective :** This clinical study aims at comparing two different preventive treatments of graft-versus-host disease (GVHD) that occurs after hematopoietic stem cell transplantation prepared by reduced-intensity conditioning : the Tacrolimus-MMF and the Tacrolimus-Sirolimus combinations. This will allow physicians to determine which of these two immunosupressive treatments is the most effective and give rise to the fewest adverse events. **Primary outcome :** To compare the 1-year progression-free survival between the 2 arms (patients receiving Tacro-MMF vs patients receiving Tacro-Sirolimus) in the whole group of patients and separately in those conditioned with Flu-TBI or Flu-Bu-ATG. **Disease :** Hematological malignancies **Treatment :** Preventive treatment of graft-versus-host disease (GVHD) : • Tacro-MMF : Tacrolimus (Prograft®) + Mycophenolate mofetil (Cellcept®) • Tacro-Sirolimus : Tacrolimus (Prograft®) + Sirolimus (Rapamune®)
Principal inclusion criteria	• Male or female. • Age: 18-75 years old. • Hematological malignancies confirmed histologically and not rapidly progressing. • Theoretical indication for a standard allo-transplant, but not feasible. • Donor related to the recipient (sibling, parent, child) or unrelated, fullfils criteria for allogeneic PBSC donation according to standard procedures. • Good performance status. • Fertile patients must use a reliable contraception method. • Informed consent given by patient or his/her guardian if indicated.

Type of trial	**Phase**	2
	Number of patients	200
	Patient allocation	Patients are randomized
	Blinding to treatment	No

Protocol N°	**BHS number**	**EC number**	**EUDRACT**	**ClinicalTrial.org**
	TC-07	TJB1016	2010-024297-19	NCT01428973

Principal investigator and sponsor	**Principal investigator**		**Sponsor**
	Name	**Institution**	CHU de Liège
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Participating centres	• AZ Sint-Jan, Brugge (**Dr Selleslag, Dr Lodewyck**) • CHU de Liège, Liège (**Dr Beguin, Dr Baron, Dr Willems**) • Cliniques universitaires de Mont-Godinne, Yvoir (**Dr Graux**) • Cliniques universitaires St Luc UCL, Bruxelles (**Dr Poiré**) • H.-Hartziekenhuis Roeselare-Menen vzw, Roeselare (**Dr Deeren**) • Hôpital de Jolimont, Haine-St-Paul (**Dr Straetmans**) • Institut Bordet, Bruxelles (**Dr Lewalle, Dr Firescu**) • UZ Antwerpen, Antwerpen (**Dr Berneman, Dr Schroyens**) • UZ Brussel, Brussel (**Dr Schots, Dr De Becker**) • UZ Gasthuisberg KUL, Leuven (**Dr Maertens**) • UZ Gent, Gent (**Dr Noens, Dr Kerre**) • ZNA Stuivenberg, Antwerpen (**Dr Zachée**)	
Status	**Start of study**	September 2011
	Approximate duration	5 years (+ 5 years of follow-up)