Clinical trial TC01.

Title	Allogeneic hematopoietic cell transplantation with HLA-matched donors : a phase II randomized study comparing 2 nonmyeloablative conditionings			
Summary	**Objective :** This clinical study aims at comparing two nonmyeloablative conditioning regimens (FLU-TBI or TLI-ATG) in patients affected by hematological malignancies treated with allogeneic hematopoietic stem cell transplantation from HLA-matched donors. This will allow physicians to determine which of these conditionings is associated with the lowest incidence of acute graft-versus-host disease (GVHD) and is thus likely to improve the survival of patients. **Primary outcome :** To compare the incidence of grade II-IV acute GVHD between patients receiving FLU-TBI conditioning and patients receiving TLI-ATG conditioning. **Disease :** Hematological malignancies **Treatment :** Two nonmyeloablative conditioning regimens : • FLU-TBI : single dose total body irradiation + chemotherapeutic drug (fludarabine) • TLI-ATG : total lymphoid irradiation (10 days) + anti-thymocyte globulins			
Principal inclusion criteria	• Male or female. • Age ≤ 75years. • 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 of minor age.			
Type of trial	**Phase**	2		
	Number of patients	100		
	Patient allocation	Patients are randomized		
	Blinding to treatment	No		
Protocol N°	**BHS number**	**EC number**	**EUDRACT**	**ClinicalTrial.org**
	TC-01	TJB0702	2007-002548-12	NCT00603954
Principal investigator and sponsor	**Principal investigator**		**Sponsor**	
	Name	**Institution**	CHU de Liège	
	Pr Frédéric Baron	CHU de Liège		

<table>
<tr><td>Participating centres</td><td colspan="2">• AZ Maastricht, Maastricht (Dr Schouten)
• 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)
• 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)</td></tr>
<tr><td rowspan="2">Status</td><td>Start of study</td><td>January 2008</td></tr>
<tr><td>Approximate duration</td><td>3 years (+ 2 years of follow-up) – Recruitment now completed</td></tr>
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