Clinical trial TC06.

Title	Prevention and treatment of severe GVHD after allogeneic hematopoietic stem cell transplantation, applied as consolidation immunotherapy in patients with hematological malignancies. A prospective randomized phase III trial	

Summary	**Objective :** This clinical study includes two parts. The first part aims at determining if using a time restricted immunosuppressive regimen as compared to a standard one in patients after allogeneic hematopoietic stem cell transplantation could enhance graft-versus-leukemia (GVL) effect without compromising this by a substantial increase of acute graft-versus-host disease (GVHD). The second part aims at improving the response rate to treatment of severe acute GVHD by adding ATG-Fresenius to standard high dose prednisolone, an anti-inflammatory drug used as first-line treatment of this disease.
	
	Primary outcome :
	• 1st part of the study: Proportion of patients with non-severe GVHD (acute GVHD grade I, grade II without gut infiltration, or chronic GVHD not requiring systemic treatment) within day180 after randomization / registration.
	• 2nd part of the study: Proportion of patients in each treatment arm who experience a complete remission from GVHD or partial remission from GVHD at day 28 without treatment failure (initiation of secondary treatment).
	
	Disease : Hematological malignancies
	
	Treatment :
	• 1st part of the study :
	  o Myfortic® + cyclosporine A (time restricted immunosupression)
	  o Myfortic® + cyclosporine A (prolonged standard immunosupression)
	• 2nd part of the study : **now closed**	

Principal inclusion criteria	• For randomization 1 :
	  o Male or female.
	  o Age: 18-65 years old.
	  o Hematological malignancies.
	  o Planned allogeneic stem cell transplantation.
	  o Additional for randomization: A planned unmanipulated (non-T-cell depleted) allogeneic SCT.
	  o Additional for registration: A planned T-cell depleted allogeneic SCT.
	  o Related or unrelated donor with a 8/8 HLA match (HLA A, B, C, DRB1).
	  o Good performance status.
	  o Female patients are non-pregnant.
	  o Informed consent given by patient.
	• For randomization 2 : **now closed**	

Type of trial	**Phase**	3
	Number of patients	• 1st randomization : 400 (internationally) • 2nd randomization : 110 (internationally)
	Patient allocation	Patients are randomized
	Blinding to treatment	No

<table>
<tr><td rowspan="2">Protocol N°</td><td>BHS number</td><td>EC number</td><td>EUDRACT</td><td>ClinicalTrial.org</td></tr>
<tr><td>TC-06</td><td>Hovon 96 GVHD</td><td>2008-003540-11</td><td>----------</td></tr>
<tr><td rowspan="3">Principal investigator and sponsor</td><td colspan="2">Principal investigator</td><td colspan="2">Sponsor</td></tr>
<tr><td>Name</td><td>Institution</td><td colspan="2" rowspan="2">Hovon</td></tr>
<tr><td>Pr Johan Maertens</td><td>UZ Gasthuisberg
KUL</td></tr>
<tr><td>Participating centres</td><td colspan="4">• CHU de Liège, Liège (<u>Dr Beguin, Dr Baron, Dr Willems</u>)
• H.-Hartziekenhuis Roeselare-Menen vzw, Roeselare (<u>Dr Deeren</u>)
• UZ Gasthuisberg KUL, Leuven (<u>Dr Maertens</u>)
• ZNA Stuivenberg, Antwerpen (<u>Dr Zachée</u>)</td></tr>
<tr><td rowspan="2">Status</td><td colspan="2">Start of study</td><td colspan="2">October 2010</td></tr>
<tr><td colspan="2">Approximate duration</td><td colspan="2">3 years (+ 5 years of post-transplant follow-up)</td></tr>
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