Clinical trial TC03.

<table>
<tr><td>Title</td><td colspan="4">Co-transplantation of mesenchymal stem cells and HLA-mismatched allogeneic hematopoietic cells after nonmyeloablative conditioning: a phase II randomized double-blind study</td></tr>
<tr><td>Summary</td><td colspan="4"><u>Objective :</u> This clinical study aims at evaluating if an intravenous injection of mesenchymal stem cells could improve the survival of patients affected by haematological malignancies undergoing allogeneic hematopoietic stem cell transplantation from a partially compatible donor after nonmyeloablative conditioning. For that purpose, MSC will be injected on the day of HSC transplantation.

<u>Primary outcome :</u> To compare 1-year overall survival between patients receiving MSC and patients receiving placebo.

<u>Disease :</u> Hematological malignancies

<u>Treatment :</u> Mesenchymal stem cells (MSC) or placebo

Mesenchymal stem cells (MSC) are stem cells that normally give rise to bone, cartilage and fat, but they also have immunosuppressive properties. They can be cultured from the bone marrow of normal volunteers, do not need to be HLA-matched with the patient and can be injected intravenously without significant side effects.</td></tr>
<tr><td>Principal inclusion criteria</td><td colspan="4">• Male or female.
• Age ≤ 75 years.
• Hematological malignancies confirmed histologically and not rapidly progressing.
• Theoretical indication for a standard allo-transplant, but not feasible.
• Good performance status.
• Fertile patients must use a reliable contraception method during and for 12 months following treatment.
• Donor related to the recipient (sibling, parent, child) or unrelated, fullfils criteria for allogeneic PBSC donation according to standard procedures.
• Informed consent given by patient or his/her guardian if of minor age.</td></tr>
<tr><td rowspan="4">Type of trial</td><td>Phase</td><td colspan="3">2</td></tr>
<tr><td>Number of patients</td><td colspan="3">120</td></tr>
<tr><td>Patient allocation</td><td colspan="3">Patients are randomized</td></tr>
<tr><td>Blinding to treatment</td><td colspan="3">Yes (both for the patient and for the medical staff)</td></tr>
<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-03</td><td>TJB0909</td><td>2009-014980-38</td><td>NCT01045382</td></tr>
<tr><td rowspan="2">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">CHU de Liège</td></tr>
<tr><td>Pr Frédéric Baron</td><td>CHU de Liège</td></tr>
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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 St Luc UCL, Bruxelles (**Dr Poiré**) • 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**	July 2010
	Approximate duration	4 years (+ 2 years of follow-up)