Clinical trial TC04.

<table>
<tr><td>Title</td><td colspan="4">A pilot study to assess the feasibility of unrelated umbilical cord blood transplantation with coinfusion of third-party mesenchymal stem cells after myeloablative or nonmyeloablative conditioning in adult patients with hematological malignancies</td></tr>
<tr><td>Summary</td><td colspan="4"><u>Objective :</u> This clinical study proposes to infuse mesenchymal stem cells on the day of umbilical cord blood transplantation in order to improve engraftment and to reduce the risk of graft rejection. As it is one of the first studies where mesenchymal stem cells are employed within the framework of umbilical cord blood transplantation, it principally aims at evaluating both the feasibility and security of this approach.

<u>Primary outcome :</u> To determine the feasibility of UCB HSCT with co-infusion of third party mesenchymal stem cells as assessed by the treatment-related mortality at day 100 after transplant.

<u>Disease :</u> Hematological malignancies

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

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: 15-60 years old.
• Hematological malignancies not rapidly progressing.
• Allogeneic stem cell transplantation is the preferred treatment option.
• No peripheral blood or marrow donor available at the 9/10 compatibility level using high resolution typing techniques.
• Adequate cord blood transplant available.
• Good performance status.
• Female patients are non-pregnant.
• 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">1 - 2</td></tr>
<tr><td>Number of patients</td><td colspan="3">20</td></tr>
<tr><td>Patient allocation</td><td colspan="3">Only one group (single-arm study)</td></tr>
<tr><td>Blinding to treatment</td><td colspan="3">No</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-04</td><td>BHS-UCB2009</td><td>2009-011817-26</td><td>NCT01092026</td></tr>
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<tr><td rowspan="3">Principal investigator and sponsor</td><td colspan="2">Principal investigator</td><td>Sponsor</td></tr>
<tr><td>Name</td><td>Institution</td><td rowspan="2">UZ Brussel</td></tr>
<tr><td>Pr Rik Schots</td><td>UZ Brussel</td></tr>
<tr><td>Participating centres</td><td colspan="3">• AZ Sint-Jan Brugge, Brugge (<u>Dr Selleslag, Dr Lodewyck</u>)
• CHU de Liège, Liège (<u>Dr Beguin, Dr Baron, Dr Willems</u>)
• Cliniques universitaires St Luc UCL, Bruxelles (<u>Dr Poiré</u>)
• Institut Bordet, Bruxelles (<u>Dr Lewalle, Dr Firescu</u>)
• UZ Antwerpen, Antwerpen (<u>Dr Berneman, Dr Schroyens</u>)
• UZ Brussel, Brussel (<u>Dr Schots, Dr De Becker</u>)
• UZ Gasthuisberg KUL, Leuven (<u>Dr Maertens</u>)
• UZ Gent, Gent (<u>Dr Noens, Dr Kerre</u>)</td></tr>
<tr><td rowspan="2">Status</td><td colspan="2">Start of study</td><td>November 2010</td></tr>
<tr><td colspan="2">Approximate duration</td><td>4 years</td></tr>
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