Clinical trial TC08.

<table>
<tr><td>Title</td><td colspan="4">Busulfan dosage in allogeneic stem cell transplant recipients receiving PO Busulfan containing conditioning regimens</td></tr>
<tr><td>Summary</td><td colspan="4"><u>Objective :</u> This clinical study aims at validating an experimental busulfan (a chemotherapeutic drug) dosing method that has been set up in the Ghent University Hospital. The study is designed to determine if it is possible to obtain reliable results by applying this technique to blood samples coming from different belgian hospitals. This promising dosing method could help to better determine the optimal dose of busulfan that has to be employed as a conditioning regimen in patients undergoing allogeneic or autologous stem cell transplantation.

<u>Primary outcome :</u>
• To validate the busulfan dosing method that has been set up in the Ghent University Hospital in Adult Belgian Stem Cell Transplantation Centers.
• To evaluate the feasibility to get the samples in time in Ghent.

<u>Disease :</u> Hematological malignancies (any malignancy)

<u>Treatment :</u> none (observational study)</td></tr>
<tr><td>Principal inclusion criteria</td><td colspan="4">• Male or female.
• Any age.
• Any malignancy.
• Any conditioning containing busulfan.</td></tr>
<tr><td rowspan="4">Type of trial</td><td>Phase</td><td colspan="3">Observational study</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">Not applicable</td></tr>
<tr><td rowspan="2">Protocol N°</td><td>BHS number</td><td>EC number</td><td>B number</td><td>ClinicalTrial.org</td></tr>
<tr><td>TC-08</td><td>BHS-TC08</td><td>Pending</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">UZ Gent</td></tr>
<tr><td>Dr Tessa Kerre</td><td>UZ Gent</td></tr>
<tr><td>Participating centres</td><td colspan="4">• CHU de Liège, Liège (<u>Dr Beguin, Dr Baron, Dr Willems</u>)
• Cliniques universitaires St Luc UCL, Bruxelles (<u>Dr Poiré</u>)
• UZ Gasthuisberg KUL, Leuven (<u>Dr Maertens</u>)
• UZ Gent, Gent (<u>Dr Noens, Dr Kerre</u>)</td></tr>
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Status	**Start of study**	April 2012
	Approximate duration	1 year