INFUSION OF THIRD-PARTY MESENCHYMAL STEM CELLS (MSC) AFTER KIDNEY AND LIVER TRANSPLANTATION: A PHASE I-II, OPEN-LABEL, CLINICAL STUDY (EudraCT 2011-001822-81 & NCT01429038)

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MSC cells have demonstrated significant immunosuppressive effects in various *in vivo* and *in vitro* studies. This study aims to be the first evaluation of the safety and tolerability of third party MSC infusion after cadaveric kidney and liver transplantation in a prospective phase I-II study, taking advantage of our centre expertise and experience in MSC use in graft-versus-host disease (GVHD) after bone marrow transplantation and using an already functioning GMP-compliant laboratory producing clinical-grade MSC. Secondary end-points will help to evaluate the immunosuppressive potential of MSC after organ transplantation, and the opportunity to develop larger randomised, controlled, phase III trials.

After successful transplantation, 10 liver and 10 kidney transplant recipients under standard immunosuppression (tacrolimus, MMF, steroids) will receive an intravenous infusion of 1.5-3x10^6/kg of third-party MSC on post-operative day 3±2. These patients will be prospectively compared to 10 liver and 10 kidney recipients who meet the inclusion criteria but deny MSC infusion. Safety will be assessed by recording side effects, including opportunistic infections and cancers. Immunosuppressive potential will be evaluated by rejection episode rates, by graft/patient survivals, by immunohistology of 3-months kidney and 6-month liver graft biopsies and by *in vitro* evaluation of the immunity profile of the recipients. In a second step, reduction (kidney) and progressive weaning (liver) of immunosuppression will be attempted in recipients who received MSC.

This ongoing study is supported by research grants from the CHU of Liège, University of Liège, and by the Senior Clinical Research Grant from ESOT. The first patients were included and treated in early 2012, and final results expected in late 2013.