Protocol Amendment # 003

Proposed by: *RPC Groningen* **Date:** *15-03-2005*

Title: *Viability assessment of donor kidneys undergoing hypothermic machine perfusion preservation*

Background and Aim

Machine perfusion (MP) may not only be a superior preservation method for marginal kidneys. It also offers the unique opportunity to assess isolated donor organs prior to transplantation, thus being a possible diagnostic tool for the transplant surgeon. So far, however, there is no scientifical consensus about which parameters and markers are relevant for the assessment of machine perfused donor kidneys. The aim of this amendment is to measure several perfusate parameters known to be possibly related to organ quality and correlate them with new biomarkers and clinical follow-up data, to allow so the development of a clinically relevant and practical kit of MP viability assessment markers for future use in clinical routine.

Method

From each MP procedure, perfusate samples will be taken at 0 and 1 hours after the start of perfusion. Another perfusate sample will be taken at the end of the MP procedure. Each sample will contain 10 ml of perfusate and will be taken by the perfusionist to be stored on ice. Perfusate samples will be collected and transported to the respective RPC and stored at –80ºC. Samples will be collected at regular intervals and analyzed at the end of the trial at the Groningen RPC.

Analysis will consist of:

- *LDH*
- *lactate*
- *von Willebrand factor*
- *alanine-aminopeptidase*
- *alpha-GST*

Statistics

All measured parameters will be correlated to organ quality assessment by the transplant surgeon, donor and recipient demographics, perfusion pressure/flow read-out, post-transplant function, patient and graft survival, and acute rejection using a MVA.

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