

# Machine Preservation Trial

MP vs. CS in Kidney Transplantation in collaboration with Eurotransplant



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## Sponsor

Organ Recovery Systems

## Protocol Amendment # 004

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

**Title:** *Correlation of donor plasma and serum markers to transplant outcome after machine perfusion and cold storage of kidney grafts*

### Background and Aim

*In order to assess relevant influence of machine perfusion (MP) on transplant outcome, not only general donor parameters are important. Highly specific markers in the donor plasma/serum can give insight into possible pre-procurement injury of the kidney parenchyma and/or endothelium and allow assessment which factors render the organ more susceptible to deterioration during cold storage (CS). Aim of this amendment is to correlate the markers mentioned below to transplant outcome after MP to clarify which donor kidneys will benefit most from MP.*

### Method

*Before each donor operation, two 10 ml whole blood samples (1 EDTA, 1 no additives) of the donor will be taken. Samples are collected by the perfusionist and will be stored at room temperature. Blood samples will be taken to the respective RPC, spinned and the plasma / serum stored at -80°C. At the end of the trial all samples will be sent to the Groningen RPC and prepared for analysis.*

*Analysis of the donor serum will consist of:*

- *IL-6 / TNF-alpha*
- *Von Willebrand factor*
- *CRP*
- *T3 / T4 / TSH*
- *Fabs*
- *vasopressine*
- *lactate*
- *glucose*
- *KIM-1*

### Statistics

*All measured parameters will be correlated to organ quality assessment by the transplant surgeon, post-transplant delayed graft function (DGF), patient survival, graft survival and occurrence of acute rejection. MP preservation is the experimental group, CS preservation will be the control group.*