Protocol Amendment # 001

Proposed by: *RPC Groningen* **Date:** *01-03-2005*

Title: *Parenchymal and endothelial cell injury during machine perfusion of kidney grafts*

Background and Aim

Machine perfusion is thought to reduce catabolism and support anabolic metabolism in the kidney graft, thus potentially reducing the amount of injury caused by cold ischemia. MP itself, however, may also introduce a new kind of damage to the organ, as vascular endothelium experiences shear stress of the cold preservation medium. The purpose of this amendment is to gain better insight in the nature of MP-specific tissue injury and which processes significantly contribute to this type of damage to the kidney graft and possibly affectviability and posttransplant function.

Method

From each kidney graft subjected to MP two hollow needle biopsies will be taken; one after procurement, immediately prior to the start of MP, the other one hour after reperfusion, or immediately prior to closure (time should be noted). All tissue biopsies will be obtained by the responsible surgeon and collected by the perfusionist on duty. One half of the biopsy will be submerged in formalin, the other half will be stored in RNA later. At regular intervals stored biopsies will be bulk shipped to or recovered by the RPC Groningen for analysis.

Analysis will consist of histological & molecular biological examination of the kidney parenchyma and endothelium, focusing on endothelial cell damage and parenchymal signs of injury. Possible injury will be related to donor and recipient demographics as well as to posttransplant functional results.

Statistics

Histological signs of endothelial cell damage and parenchymal injury in the MP group will be compared to a control group of CS kidneys biopsies and their deviance from golden standard living donorkidneys will be noted, testing for significant differences between MP and CS in terms of injury to the kidney graft.

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