FINAL STUDY REPORT

PROTOCOL TITLE:

Quantitative Assessment of Myocardial Perfusion with Magnetic Resonance Using an Intravascular Contrast Agent

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After submitting the MR datasets acquired in the first group of patients to the IMP provider of the trial (Bayer Schering Pharma, BSP), it was seen that the image quality of the perfusion data acquired during infusion of Vasovist was not superior to the image quality obtained during infusion of Gadovist. Furthermore, in consideration of the lower signal to noise ration obtained with Vasovist despite injecting the maximum dose approved for the study, on the 24/11/2010 it was decided that early termination of the study was the most appropriate course of action.

Justification for early termination of the trial: low efficacy of the investigational contrast agent (Vasovist) for the acquisition of first-pass perfusion images.

No patients were still receiving the treatment at time of early termination.

We can conclude that Vasovist, injected at 0.12 ml/kg of bw, does not allow the acquisition of first pass perfusion images of the heart with comparable image quality and signal-to-noise ratio when compared to Gadovist.

London, 2 November 2011 Prof. Eike Nagel