

MEETING ABSTRACT

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Custodiol - N versus Custodiol: a prospective randomized double blind multicenter phase III Trial

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Background/Introduction

HTK-Solution (Custodiol) is a well-established cardioplegic and organ preservation solution. We currently developed a novel HTK based solution Custodiol-N which includes iron chelators to reduce oxidative injury as well as L-arginine, to improve endothelial function.

Aims/Objectives

In the present first-in-human study, Custodiol-N was compared with Custodiol in patients undergoing elective coronary bypass surgery.

Method

The study was designed as prospective randomized double blind non-inferiority trial. Primary end-point was area under the curve (AUC) of creatine kinase MB (CKMB) within the first 24 hours after surgery. Secondary endpoints included, peak CKMB and troponin-T and AUC of troponin-T release, cardiac index, cumulative catecholamine dose, ICU-stay and mortality. All values are given as mean \pm SD, $p < 0.05$ was considered as statistically significant.

Results

Early termination of the trial was performed per protocol as the primary non-inferiority end point was reached after inclusion of 101 patients. Patient characteristics, medical history, operation and cross-clamp times did not differ between the groups. CKMB AUC (878 ± 549 vs. 778 ± 439 h*U/l, non-inferiority $p < 0.001$) and Troponin-T

AUC (12990 ± 8347 vs. 13498 ± 6513 h*pg/ml, non-inferiority $p < 0.001$) was similar in both groups. Although the trial was designed for non-inferiority, peak CKMB (52 ± 40 vs. 41 ± 30 U/l, superiority $p < 0.002$) was significantly lower in the Custodiol-N group. Cardiac index, catecholamines ICU-stay and mortality (1 death in the control group) was similar in both groups.

Discussion/Conclusion

This study shows that Custodiol-N is safe and provides similar cardiac protection as the established HTK-Custodiol solution. The significantly reduced peak CKMB levels in the Custodiol-N group may implicate a beneficial effect on ischemia/reperfusion injury in the setting of coronary bypass surgery.

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