SYNOPSIS

Title of study: Comparison between the administration of Levosimendan or placebo in the preparation of critical patients who must undergo cardiac surgery
EudraCT Number: 2009-011779-65
Sponsor Protocol Number: ACA-SPAI-2008-20
Sponsor Name: Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau

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Publication (reference): none.

Introduction: The aim of this study was to evaluate the effects of preoperative use of levosimendan versus placebo in the reduction of mortality and severe morbidity in patients with chronic cardiac insufficiency.
The trial terminated early due to lack of subjects recruitment and only partial results are available.

Material and methods: Multicenter, national, randomized, double blind clinical trial. The patients were undergoing coronary revascularization alone or with mitral valve repair or replacement due to ischemic mitral insufficiency, had a left ventricular ejection fraction (LVEF) less than 35% and required extracorporeal circulation. Placebo or levosimendan was administrated at 0.1 ug/kg/min during 12h previous to surgery. Mortality was analyzed at 30, 60, 180 days, 1 year and 2 years. Severe morbiditiy was evaluated at 30 days.

Results: Thirty four patients received the infusion from February 2011 to august 2012. Two of them were not included because they had a different surgical procedure than the one proposed in the study. Thirty two patients were analyzed. Both groups were homogeneous in demographic data, toxic habits, surgical risk score (Euroscore I), ASA and NYHA classification.

Table I

	Levosimendan N=17 (%)	**Placebo N=15 (%)**	**p**
Survival 30 days	16 (94,10)	0 (100)	1,000
AMI	Not available		
HF with MV	1 (7,10)	0 (0)	0,467
HF with inotropic	3 (21,40)	2 (12,50)	0,642
ARF	2 (14,30)	2 (12,50)	1,000
IABP or drugs during CPB	2 (14,30)	2 (13,30)	1,000
Sepsis	2 (14,30)	0 (0)	0,209
VM > 48h	Not available		
VM > 72h	1 (7,10)	0 (0)	0.467
Gastrointestinal complications	Not available		
Stroke	Not available		

Acute Myocardial Infarction (AMI) Heart failure (HF) mechanical ventilation (MV) Acute Renal Failure (ARF) Intra-aortic balloon pump (IABP) cardiopulmonary bypass (CPB)

No significant statistical differences were observed in mortality at 30 days or in serious complications analyzed.

Conclusions: Considering the results obtained, we cannot affirm that preoperative treatment with levosimendan in patients who undergo by pass graft alone or with mitral valve repair or replacement due to ischemic mitral insufficiency and LVEF < 35%, may improve outcome. Nevertheless, a reduced trend of heart failure, sepsis and prolonged mechanical ventilation was observed in the levosimendan group.
New studies with a higher number of patients are required to confirm this tendency.