Posting of result-related information to EudraCT: Summary attachment

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Trial information

Title: Effect of levosimendan or placebo on exercise capacity and hemodynamics in patients with advanced chronic heart failure (LOCO-CHF trial).

EudraCT number: 2017-002049-31.

Clinicaltrials ID: NCT03576677.

Sponsor details: Professor Finn Gustafsson MD, PhD, DMSc. Department of Cardiology, Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark.

General information about the trial: A prospective, multi-center, double-blinded, placebo controlled, randomized study with the purpose to evaluate the subacute effect of levosimendan infusion on exercise capacity and exercise hemodynamics compared with placebo in adult patients with advanced chronic heart failure. The primary outcome was change in CO/PCWP from day 0 to day 5 ($\Delta CO/PWCP^{day0\text{-}day5}$) obtained by hemodynamic measurements (performed by Swan Ganz catheter) after 6 hours infusion of levosimendan/placebo and at the workload corresponding to 50% of pVO2 (=submax exercise; determined at baseline test) during supine exercise test. Total follow-up period was 30 days.

Intervention: Infusion of levosimendan 0.2 µg/kg/min (no bolus) for 6 hours *or* placebo.

Number of subjects enrolled: Six (expected enrollment: 42 subjects). Two subjects did not complete the exercise test with invasive hemodynamic measurement at day 5 to allow for evaluation of the primary endpoint.

Trial status: The trial was stopped prematurely due to a number of resource related issues and thus only partial results are available and full analyses as per protocol have not been conducted.

Study population baseline characteristics

	N = 6
Patient characteristics	
Age (years)	60.5 (53.0-72.0)
Male sex (n, %)	6 (100%)
LVEF (%)	20.0 (15.0-35.0)
BMI (kg/m^2)	25.4 (25.3-26.1)
Heart rate (bpm)	68.5 (61.0-81.0)

Systolic blood pressure (mmHg)	115 (95-124)
Diastolic blood pressure (mmHg)	71 (67-79)
NYHA class	
1 (n, %)	0 (0%)
2 (n, %)	0 (0%)
3 (n, %)	6 (100%)
4 (n, %)	0 (0%)
Heart failure etiology	
Ischemic (n, %)	5 (83%)
Non-ischemic (n, %)	1 (17%)
Relevant comorbidity	
Hyperlipidemia (n, %)	3 (50%)
Hypertension (n, %)	2 (33%)
Diabetes (n, %)	1 (17%)
IHD (n, %)	5 (83%)
CRT-D (n, %)	5 (83%)
CRT-P (n, %)	1 (17%)
History of smoking (n, %)	5 (83%)
Heart failure medication	
ACEi	2 (33%)
ARB	3 (50%)
Loop diuretics	6 (100%)
BB	5 (83%)
MRA	3 (50%)
ARNI	1 (17%)

Data are reported as median (IQR) or absolute number (percentage) as appropriate.

Study population baseline (day 0) supine exercise test and hemodynamic measurements

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	N = 6
Exercise test	
Heart rate rest (bpm)	65 (63-75)
Heart rate max (bpm)	111 (98-127)
Max watt	50 (35-60)
Hemodynamic measurements	
PCWP rest (mmHg)	22 (14-25)
PCWP submax (mmHg)	33 (28-43)
PCWP max (mmHg)	41 (37-43)
CO rest (L/min)	4.3 (4.0-5.0)
CO submax (L/min)	5.7 (5.5-6.3)
CO max (L/min)	7.0 (5.5-7.9)
CO/PCWP rest	0.21 (0.17-0.25)
CO/PCWP submax	0.18 (0.15-0.20)
CO/PCWP max	0.19 (0.15-0.20)

Data are reported as median (IQR) or absolute number (percentage) as appropriate.