Karolinska Institutet

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Summary attachment - study ended before 21 July 2013

EudraCT number: 2006-005220-16

Full title of the study: Cardiovascular fysiological effects of Exenatide on heart failure

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Study ended: 2010-06-16

Link to published article: https://link.springer.com/article/10.1007%2Fs00125-011-2440-x

Abstract from published article:
Aims/hypothesis: The aim of this study was to determine whether exenatide improves haemodynamic function in patients with type 2 diabetes with congestive heart failure (CHF).

Methods: The main eligibility criteria for inclusion were: male/female (18–80 years) with type 2 diabetes and CHF (ejection fraction ≤35%, and New York Heart Association functional class III or IV). Out of 237 patients screened, 20 male type 2 diabetic patients participated in this crossover trial design and were allocated (sequentially numbered) to i.v. infusions during two consecutive days with (1) exenatide (0.12 pmol/kg/min); and (2) placebo for 6 h followed by a washout period for 18 h, at Stockholm South Hospital, Sweden. Patients and researchers were blinded to the assignment. Cardiac haemodynamic variables were determined by right heart catheterisation. The primary endpoint was defined as an increase in cardiac index (CI) or a decrease in pulmonary capillary wedge pressure (PCWP) of ≥20%. Secondary endpoints were tolerability and safety of exenatide infusion.

Results: CI increased at 3 and 6 h by 0.4 ± 0.1 (23%) and 0.33 ± 0.1 (17%) l min−1 m−2, during exenatide infusion vs −0.02 ± 0.1 (−1%) and −0.08 ± 0.1 (−5%) l min−1 m−2 during placebo (p = 0.003); and heart rate (HR) increased at 1, 3 and 6 h by 8 ± 3 (11%), 15 ± 4 (21%) and 21 ± 5 (29%) beats per min (bpm), during exenatide infusion vs −1 ± 2 (−2%), 1 ± 1 (2%) and 6 ± 2 (8%) bpm, during placebo (p = 0.006); and PCWP decreased at 1, 3 and 6 h by −1.3 ± 0.8 (−8%), −1.2 ± 1 (−8%) and −2.2 ± 0.9 (−15%) mmHg, during exenatide infusion vs 0.3 ± 0.5 (2%), 1 ± 0.6 (6%) and 1.4 ± 0.7 (8%) mmHg, during placebo (p = 0.001). No serious adverse event was observed. Adverse events were reported in nine patients (six, nausea; two, increased HR; one, increased systolic blood pressure).

Conclusions/interpretation: Infusion of exenatide in male type 2 diabetic patients with CHF increased the CI as a result of chronotropy, with concomitant favourable effects on PCWP and reasonable tolerability of the drug. The clinical implications of using exenatide in patients with CHF are still not clear and further studies are warranted.

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