



## **Single-Center, Open Study on the Performance of the Software eMPC Algorithm Used for Blood Glucose Control Over an Extended Glucose Control Range (4.4 to 8.3 Mmol/L) for a Maximum of 48 Hours in Postoperative Cardiac Surgery Patients in the Intensive Care Unit**

B. Braun Melsungen AG, Hospital Care, Clinical Development

**Background:** Hyperglycaemia is commonly found in critically ill patients. Clinical studies demonstrated that tight blood glucose control in medical and surgical ICU patients results in a significant better outcome for the patients. Based on this emerging clinical evidence, there are increasing efforts worldwide to maintain strict glycaemic control in critically ill patients. However, achieving this goal requires extensive nursing efforts, including frequent bedside glucose monitoring and the implementation of complex intensive insulin infusion protocols. A fully automated algorithm may help to overcome some of these limitations by excluding intuitive interventions and integrating relevant clinical data in the decision-making process. This study will investigate the performance of an eMPC algorithm adjusted to target the range 4.4 - 8.3 mmol/L in line with the Surviving Sepsis guidelines.

**Methods:** The study is a single-center, open, non-controlled clinical investigation in twenty postoperative cardiac surgery patients at the adult intensive care unit at the Royal Brompton Hospital, London. A computer algorithm (enhanced model predictive control algorithm, eMPC) running on a laptop computer is used as decision support system to normalize the arterial blood glucose level. The eMPC suggests an infusion rate of intravenously administered human insulin based on arterial blood glucose values and on administered parenteral and enteral nutrition. Efficacy and safety are assessed by calculating percentage within the target range (4.4 to 8.3 mM), hyperglycaemic index (HGI) mean glucose and the number of hypoglycaemic episodes ( $< 2.2\text{mM}$ ).

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**Status:** Finalized as planned, data under evaluation

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**Register:**

<http://www.clinicaltrials.gov/ct2/show/NCT00882427?term=NCT00882427&rank=1>