



## **Mono-Centric, Open, Non-Controlled Study To Investigate The Feasibility Of Blood Glucose Control With The Software-Algorithm eMPC (Enhanced Model Predictive Control) In ICU Patients**

B. Braun Melsungen AG, Hospital Care, Clinical Development

**Background:** Hyperglycemia is common in critically ill patients and associated with an adverse outcome. Large randomized controlled trials have demonstrated that tight glycaemic control (TGC) reduces morbidity and mortality in this population. Based on this emerging evidence intensive insulin therapy is currently finding its way into the critical care practice. Numerous insulin infusion protocols, which are based on frequent bedside glucose monitoring, have been implemented. Recent reviews comparing different types of protocols describe widely ranging practice and difficulties in achieving TGC despite extensive efforts of the intensive care unit (ICU) staff. 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. The primary objective of the current study is to investigate the performance (efficacy) of a control algorithm for glycaemic control in ICU patients for the whole length of ICU stay.

**Methods:** The study is a single-center, open, non-controlled clinical investigation in twenty mechanically ventilated patients at the Medical University Graz. 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 6.1 mM), hyperglycaemic index (HGI) mean glucose and the number of hypoglycaemic episodes (< 2.2mM).

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**Status:** Recruitment finalized, data under evaluation

**Sponsor:** B. Braun Melsungen AG

**Register:**

<http://www.clinicaltrials.gov/ct2/show/NCT00735163?term=NCT00735163&rank=1>