



Monocentric, open study to investigate the feasibility of blood glucose control with the Space TGC system (with incorporated software–algorithm eMPC) in medical ICU patients

B. Braun Melsungen AG, Hospital Care, Clinical Development

Background: Hyperglycemia is common in critically ill patients and associated with an adverse outcome. Thus, glycaemic control is an important issue in critical care. Despite extensive efforts of the intensive care unit staff difficulties were experienced in achieving efficient and safe glucose control. 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. Space GlucoseControl (TGC system) is a decision support system which helps to achieve safe and reliable blood glucose control in the desired ranges. Information on parenteral and enteral nutrition is automatically integrated into the calculations. The primary objective of the current study is to investigate the performance and usability of the Space TGC system for glucose control in medical ICU patients.

Methods: The study is a single-center, open, non-controlled clinical investigation in medical intensive care patients at the Medical University Graz, Department for Internal Medicine. The Space TGC System is used as decision support system to normalize the blood glucose level. The Space TGC System suggests an infusion rate of intravenously administered 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 ($< 2.2\text{mM}$).

Principal investigator: Prof. Dr. Thomas R. Pieber, Landeskrankenhaus – Universitätsklinikum Graz, Graz, Austria

Status: Recruiting

Sponsor: B. Braun Melsungen AG

Register:

<http://www.clinicaltrials.gov/ct2/show/NCT01164423?term=NCT01164423&rank=1>