Biochaperone® Glucagon, A Stable Ready-to-use Liquid Glucagon Formulation Enabled by Biochaperone Technology, is Well Tolerated and Quickly Restores Euglycaemia after Insulin-induced Hypoglycaemia

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Introduction & Background
- Human glucagon is approved as an emergency rescue treatment for people with diabetes experiencing severe hypoglycaemia.
- Usability of commercially available emergency kits is limited due to the complexity of the reconstitution and administration process, especially in stressful circumstances.
- Biochaperone® Glucagon (BCG) is a stable, ready-to-inject, aqueous formulation of human glucagon for hypoglycaemia rescue therapy enabled by the Biochaperone® technology.

Aims of the study
- To assess safety and tolerability of two compositions of BCG (BCG1 and BCG2) and GlucaGen® HypoKit® (all dosed at 1 mg).
- To compare pharmacodynamic (PD) and pharmacokinetic (PK) properties of BCG1, BCG2 and GlucaGen® HypoKit®.

Methods
- Phase 1, randomised, double-blind, three-period cross over trial.
- Male or female participants with type 1 diabetes (T1DM) were allowed to participate in the trial after having given written informed consent.
- Subjects were fasted and hypoglycaemia was induced with individualized i.v. insulin infusion to reach plasma glucose (PG) levels <60 mg/dL.
- At t=0, single subcutaneous 1 mg dose of BCG1, BCG2 and GlucaGen® HypoKit® on 3 separate dosing visits were administered.
- An individualised constant insulin infusion rate (up to 4x subject’s average basal rate; same for all dosing visits) was maintained from -30 to +240 min relative to dosing.
- If PG value ≤ 55 mg/dL within 8-30 min after dosing, an i.v. dose of glucose was administered.

Figure 1: Trial overview

Demographic data
- 27 subjects with type 1 diabetes (Figure 2)
- 3 withdrawals (1 SAE, 2 personal reasons)

Figure 2: Characteristics of the study population (mean±SD)

Table 2: Pharmacodynamic parameters (plasma glucose)

Conclusions
- BCG1, BCG2 and GlucaGen® 1 mg were safe
- BCG1, BCG2 and GlucaGen® 1 mg induce rapid and marked increases in blood glucose levels after subcutaneous administration.

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