

Assessment of Infusion Set Survival of the Newly Developed Lantern Catheter in Type 1 Diabetes by Glucose Clamp Technique (a Pilot Study)

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Background and Aims

- Modern insulin therapy aims to establish glycemic control without relevant hypoglycemia.
- Physiologic insulin secretion can best be mimicked by insulin pump therapy (CSII).
- The catheter-tissue interface is the bottle neck of CSII.
- Currently infusion sets shall be changed every 2-3 days to avoid lipohypertrophy, fluctuations in insulin absorption and occlusion.
- Patients would prefer an extended wear time if stable insulin absorption could be achieved.

Study Participants

- 16 patients with type 1 diabetes
- Existing CSII therapy for at least 6 months
- Age >18 years
- BMI: 20-28 kg/m²
- HbA1c < 86mmol/mol
- Fasting C-peptide <0.3nmol/L
- Regular use of insulin aspart or glulisine for diabetes management
- No steroid or acetaminophen therapy

Study aim

The aim of the present study is to investigate clinical performance of the Lantern catheter in 16 patients with type 1 diabetes using CSII over a period of up to 7 days

Primary objective

To compare the pharmacodynamic properties of rapid acting insulin lispro after subcutaneous bolus using the Lantern catheter at days 1, 4 and 7 of catheter wear-time in subjects with type 1 diabetes under CSII treatment.

Primary endpoint:

$t_{\max(\text{GIR})}$, time to maximum glucose infusion rate on days 1, 4 and 7 of catheter wear-time

Study material



Figure 3: Abbott Libre FGM System

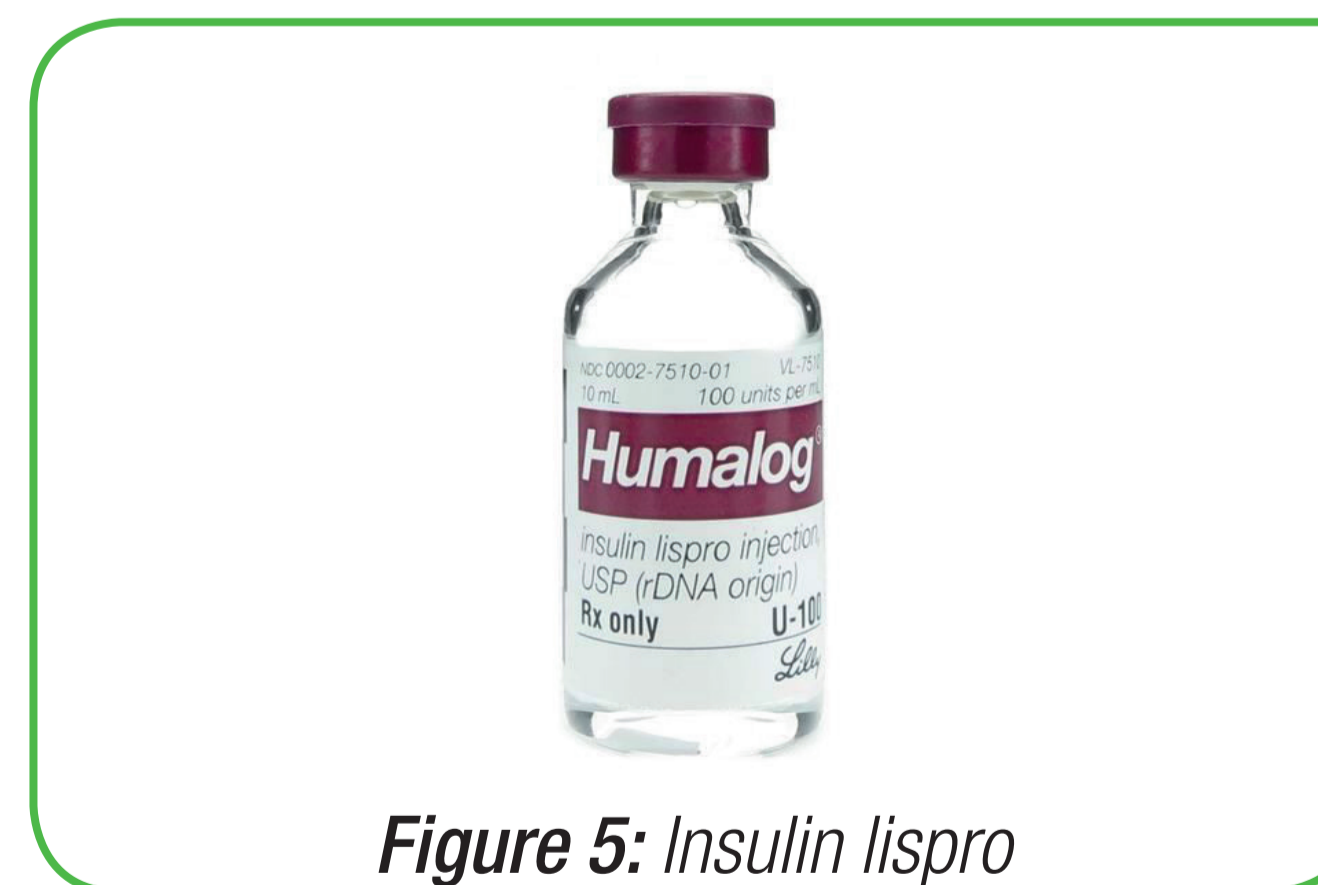


Figure 5: Insulin lispro

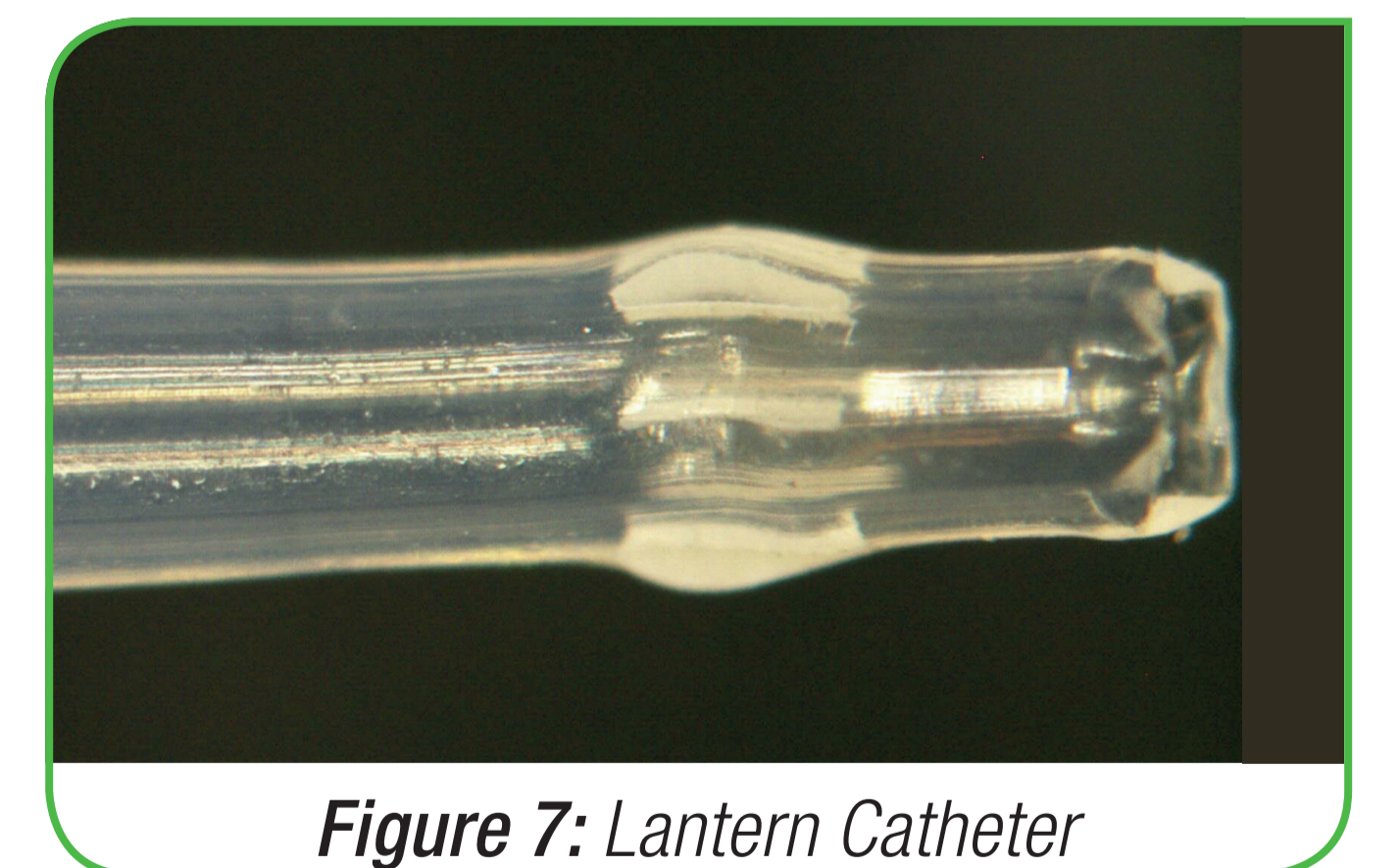


Figure 7: Lantern Catheter



Figure 4: Medtronic G640



Figure 6: Super GL 2 Analyzer



Figure 8: Conventional Catheter (Mio Infusion Set)

Study schedule

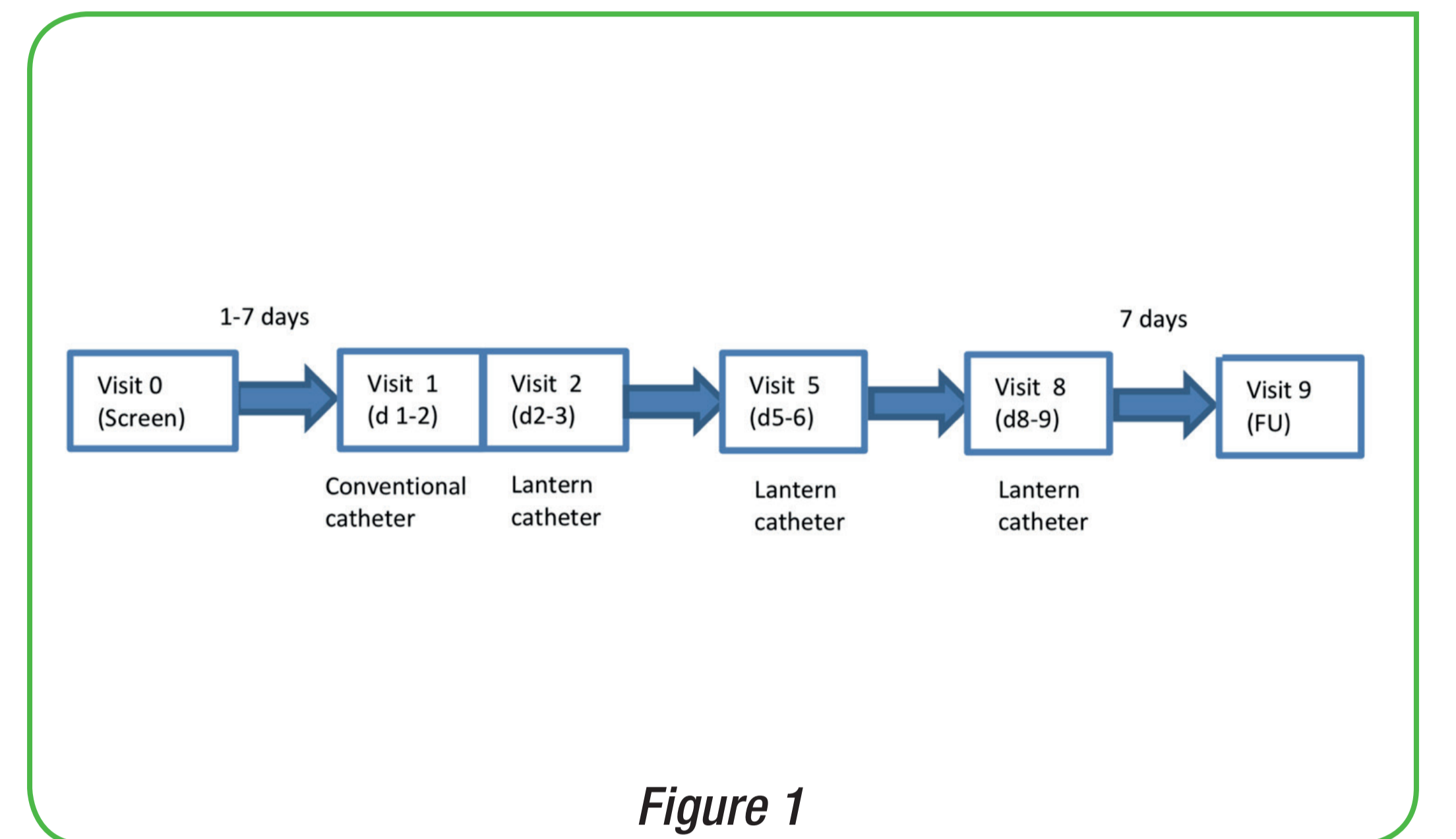


Figure 1

Clamp visit

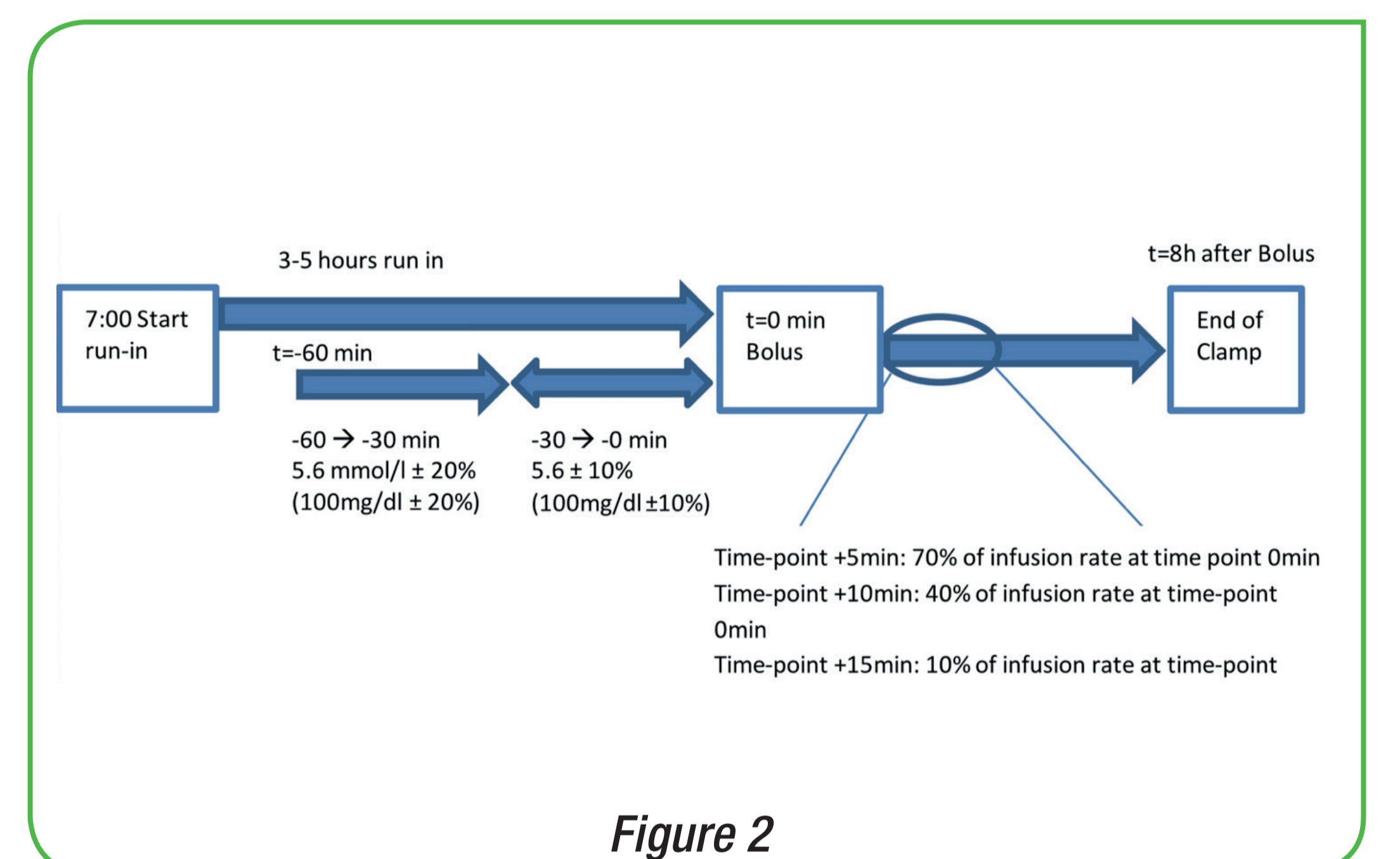


Figure 2

Study intervention

- Conventional vs. Lantern catheter for CSII (inserted immediately prior to experiment)
- CRC Phase (24 hours):**
 - Hyperglycaemic euglycaemic clamp (BG: target 5.6mmol/l ± 10%)
 - Bolus administered using insulin pump (0.15 U/kg body weight)
- Home Phase (7 days following insertion of Lantern catheter):**
 - Flash glucose monitoring
 - Subjects follow regular lifestyle

Conclusion

It is expected that the novel Lantern catheter provides stable insulin delivery over an extended wear-time of 7 days.

BMI – body mass index
CRC – clinical research centre
CSII – continuous subcutaneous insulin infusion
GIR – glucose infusion rate