**Feasibility study of a novel insulin patch pump integrated with a combined continuous glucose monitor and insulin delivering cannula – A tubeless single platform device**

**Aims**

Diabetes technology while improving glycaemia may also impose a burden upon the user. A patch pump (PP) may improve quality of life compared to conventional pumps and multiple daily injections. Combining a PP with a single insertion glucose sensing cannula (CGM-IS) may further reduce user burden. We aimed to investigate the feasibility of combining a PP with an insulin delivering cannula (PP-CGM-IS).

**Methods**

This first-in-human feasibility study evaluated PP-CGM-IS with manual insulin dosing in T1D adults using insulin pumps and CGM. An initial pilot phase studied three participants following a mixed meal test (MMT) for 12 hours. For the second phase fifteen participants were studied 72 hours, including two MMTs and one supervised free living day (FLD) at a nearby hotel. The primary outcome of interest was the accuracy of the CGM device, assessed by mean absolute relative difference (MARD). Secondary outcomes included number of insulin delivery failures, and device survival duration.

**Results**

Mean participant age was 50.1 years, 73.7% were female, and HbA1c 6.8±0.6%. Of a total of 25 devices, 7 (28%) were removed early all of which were because of sensor issues with most occurring on the first day of wear. The mean duration of pump wear in main phase was 51.2­±29.1 hours. There were no adverse events, notably no insulin delivery failures. Results of the primary endpoint, CGM accuracy, were not available at time of abstract submission. For the FLD, the mean time in range (TIR) was 62±13.2%, and blood glucose level (BGL) 9.2 ±1.1mmol/L. Total daily dose was not available at the time of abstract submission.

**Conclusion**

This first-in-human study confirms the feasibility of integrating a CGM-IS with a PP. Advancing toward a fully integrated tubeless closed-loop system warrants further research including refinement of the form-factor, algorithm implementation, and performance in real-world conditions.